Supreme Court, U.S.
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In the Supreme Court of the United States

OCTOBER TERM, 1997

TRUSERV CORPORATION, PETITIONER

v.

THE PEOPLE OF THE STATE OF CALIFORNIA, EX REL. DANIEL G. LUNGREN, ATTORNEY GENERAL, AND AS YOU SOW, RESPONDENTS

Petition for a Writ of Certiorari to the California Court of Appeal, First Appellate District

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PETITION FOR A WRIT OF CERTIORARI

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93 pp

QUESTION PRESENTED

The Federal Hazardous Substances Act (FHSA), 15 U.S.C. § 1261 note, provides that, "if a hazardous substance or its packaging is subject to a cautionary labeling requirement" imposed under the FHSA that is "designed to protect against a risk of illness or injury associated with the substance," then "no State or political subdivision may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical" to the federal requirement.

California's Proposition 65 requires businesses to provide "clear and reasonable warning" to individuals who are exposed to certain hazardous substances.

The question presented is whether the FHSA preempts an enforcement action pursuant to Proposition 65 for civil penalties and injunctive relief, which is based on a business's failure to provide warnings that are not identical to the warnings and other cautionary statements required under the FHSA for the same substance.

RULE 14.1(b) AND 29.6 STATEMENT

Petitioner TruServ Corporation, formerly known as Cotter & Company, changed its name on July 1, 1997, when it acquired Servistar Coast to Coast Corporation. TruServ has no parent company, and its only nonwholly owned subsidiary is Cotter Canada Hardware and Variety Cooperative, Inc.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

RULE 14.1 (b) AND 29.6 STATEMENT ii

TABLE OF AUTHORITIES v

OPINIONS BELOW 1

JURISDICTION 1

STATUTES AND REGULATIONS INVOLVED 1

STATEMENT 1

A. The Statutory And Regulatory Framework 2

1. The Federal Hazardous Substances Act And The Federal Toluene Regulation 2

2. Proposition 65 3

B. The Proceedings Below. 4

1. The Trial Proceedings 4

2. The Court Of Appeal's Decision 5

REASONS FOR GRANTING THE PETITION 9

I. THE DECISION BELOW CONFLICTS IN MULTIPLE RESPECTS WITH THE DECISIONS OF OTHER COURTS 9

A. Courts Are Deeply Divided Over Whether FHSA And Other Federal Statutes That Expressly Preempt State "Labeling" Requirements Nevertheless Permit States To Require Warnings Outside The Product "Label" 9

TABLE OF CONTENTS — Continued

Page

B. The Court Of Appeal's Conclusions That FHSA And FIFRA Preemption Are Not Coextensive, And That Preemption Cases Involving Common Law Claims Are Immaterial To Enforcement Actions, Conflict With The Decisions Of Other Courts . . . 14

C. The Decision Below Conflicts With Those Of Other Courts Concerning The Applicability Of *Medtronic*'s "General/Specific" Distinction Outside Of The Context Of Preemption Under The Medical Device Amendments 16

II. THE ISSUES PRESENTED ARE RECURRING AND OF ENORMOUS PUBLIC IMPORTANCE 21

III. THE COURT OF APPEAL'S DECISION IS MANIFESTLY INCORRECT 25

CONCLUSION 31

TABLE OF AUTHORITIES

Page

Cases:

Ackles v. *Luttrell*, 561 N.W.2d 573 (Neb.), pet. for cert. filed, 66 U.S.L.W. 3137 (Aug. 6, 1997) (No. 97-226) 17

Arkansas-Platte & Gulf Partnership v. *Dow Chemical Co.*, 506 U.S. 910 (1992) 19

Arkansas-Platte & Gulf Partnership v. *Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir.), cert. denied, 510 U.S. 813 (1993) 11

Askenazi v. *Hymil Manufacturing Co.*, 648 N.Y.S.2d 895 (N.Y. Sup. Ct. 1996) 18

Auto Equity Sales, Inc. v. *Superior Court of Santa Clara County*, 369 P.2d 937 (Cal. 1962) 24

Baldwin v. *Alabama*, 472 U.S. 372 (1985) 14

Beyrle v. *Finneron*, 645 N.Y.S.2d 192 (N.Y. App. Div. 1996) 11

Bice v. *Leslie's Poolmart*, 39 F.3d 887 (8th Cir. 1994) 11

Brand v. *Mazda Motor Corp.*, 1997 WL 109976 (D. Kan. Feb. 12, 1997) 18

Burch v. *Amsterdam*, 366 A.2d 1079 (D.C. 1976) 21

Burke v. *Dow Chemical Co.*, 797 F. Supp. 1128 (E.D.N.Y. 1992) 12, 13

Busch v. *Graphic Color Corp.*, 662 N.E.2d 397 (Ill.), cert. denied, 117 S.Ct. 55 (1996) . . . . . *passim*

Canty v. *Ever-Last Supply Co.*, 685 A.2d 1365 (N.J. Super. Ct. 1996) 11

TABLE OF AUTHORITIES — Continued

Page

Chemical Specialties Manufacturers Ass'n v. *Allenby*, 958 F.2d 941 (9th Cir.), cert. denied, 506 U.S. 825 (1992) . . . . . *passim*

Chemical Specialties Manufacturers. Ass'n v. *Clark*, 482 F.2d 325 (5th Cir. 1973) 22

Chemical Specialties Manufacturers Ass'n v. *Lowery*, 452 F.2d 431 (2d Cir. 1971) 22

Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992) . . . . . *passim*

Comeaux v. *National Tea Co.*, 81 F.3d 42 (5th Cir. 1996) 10, 14

Committee of Dental Amalgam Manufacturers and Distributors v. *Stratton*, 92 F.3d 807 (9th Cir. 1996), cert. denied 117 S. Ct. 754 (1997) 17

Cortez v. *MTD Products, Inc.*, 927 F. Supp. 386 (N.D. Cal. 1996) 23

D-Con Co. v. *Allenby*, 728 F. Supp. 605 (N.D. Cal. 1989) 13

DerGazarian v. *Dow Chemical Co.*, 836 F. Supp. 1429 (W.D. Ark. 1993) 13

Duplin v. *Whink Products Co.*, 1994 WL 197612 (Conn. Super. Ct. May 2, 1994) 11

Ferebee v. *Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), cert. denied, 469 U.S. 1062 (1984) 11

Goodwin v. *Bacon*, 896 P.2d 673 (Wash. 1995) 12, 13

Grenier v. *Vermont Log Buildings, Inc.*, 96 F.3d 559 (1st Cir. 1996) 21

TABLE OF AUTHORITIES — Continued

Page

Harris v. *Ford Motor Co.*, 110 F.3d 1410 (9th Cir. 1997) 17, 18

Hunnings v. *Texaco, Inc.*, 29 F.3d 1480 (11th Cir. 1994) 21, 22

Industrial Truck Ass'n v. *Henry*, 1997 W.L. 594619 (9th Cir. Sept. 29, 1997) 16, 18

Jenkins v. *Amchem Products, Inc.*, 886 P.2d 869 (Kan. 1994), cert. denied, 116 S. Ct. 80 (1995) 12, 13

Jenkins v. *James B. Day & Co.*, 634 N.E.2d 998 (Ohio 1994) 11

Kernats by Kernats v. *Smiths Industries Medical Systems, Inc.*, 669 N.E.2d 1300 (Ill. App. Ct.), appeal denied, 675 N.E. 2d 634 (Ill. 1996), pet. for cert. filed, 65 U.S.L.W. 3632 (Mar. 4, 1997) (No. 96-1405) 21

King v. *E.I. Dupont De Nemours & Co.*, 996 F.2d 1346 (1st Cir.), cert. dismissed, 510 U.S. 985 (1993) 11

Kordel v. *United States*, 335 U.S. 345 (1948) 27

Kuiper v. *American Cyanamid*, 913 F. Supp. 1236 (E.D. Wis. 1996) 13

Lacey v. *Lorillard Tobacco Co.*, 956 F. Supp. 956 (N.D. Ala. 1997) 23

Lee v. *Boyle-Midway Household Products, Inc.*, 792 F. Supp. 1001 (W.D. Pa. 1992) 11

TABLE OF AUTHORITIES — Continued

Page

Lewis v. *American Cyanamid Co.*, 682 A.2d 724 (N.J. Super. Ct. App. Div. 1996), cert. granted, 697 A.2d 546 (N.J. 1997) 18

Lowe v. *Sporicidin International*, 47 F.3d 124 (4th Cir. 1995) 12

Lynnbrook Farms v. *Smithkline Beecham Corp.*, 79 F.3d 620 (7th Cir.), cert. denied 117 S. Ct. 178 (1996) 23

MacDonald v. *Monsanto*, 27 F.3d 1021 (5th Cir. 1994) 11, 15

Macrie v. *SDS Biotech Corp.*, 630 A.2d 805 (N.J. Super. App. Div.), cert. denied, 636 A.2d 522 (N.J. 1993) 13

Malone v. *American Cyanamid Co.*, 649 N.E.2d 493 (Ill. Ct. App.), appeal denied, 657 N.E. 2d 624 (Ill. 1995) 13

Medtronic, Inc. v. *Lohr*, 116 S. Ct. 2240 (1996) . . . . . *passim*

Mitchell v. *Collagen Corp.*, 1997 WL 584550 (7th Cir. Sept. 23, 1997) 17, 20, 21

Moe v. *MTD Products, Inc.*, 73 F.3d 179 (8th Cir. 1995) 23

Moore v. *B&C Family Center, Inc.*, 272 N.W.2d 150 (Mich. Ct. App. 1978) 22

Morales v. *Trans World Airlines*, 504 U.S. 374 (1992) 16, 18

Moss v. *Parks Corp.*, 985 F.2d 736 (4th Cir.), cert. denied, 509 U.S. 906 (1993) 2, 11, 14

New York State Pesticide Coalition, Inc. v. *Jorling*, 874 F.2d 115 (2d Cir. 1989) 12

TABLE OF AUTHORITIES — Continued

Page

Oja v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) 17

Papas v. *Upjohn*, 985 F.2d 516 (11th Cir.), cert. denied, 510 U.S. 913 (1993) 9. 12, 13

Papas v. *Zoecon Corp.*, 505 U.S. 1215 (11th Cir. 1992) 19

Papike v. *Tambrands Inc.*, 107 F.3d 737 (9th Cir. 1997), pet. for cert. filed, 66 U.S.L.W. 3107 (July 15, 1997) (No. 97-94) 17

Pilot Life Insurance. Co. v. *Dedeaux*, 481 U.S. 41 (1987) 18

Pinckney v. *Zep Manufacturing Co.*, 1997 WL 204903 (N.D.N.Y. Apr. 15, 1997) 22

Salazar v. *Whink Products Co.*, 881 P.2d 431 (Colo. Ct. App. 1994), cert. denied, 514 U.S. 1004 (1995) 11

San Diego Building Trades Council v. *Garmon*, 359 U.S. 236 (1959) 18, 19

Schuver v. *E.I. du Pont de Nemours & Co.*, 117 S. Ct. 274 (1996) 19

Shaw v. *Dow Brands, Inc.*, 994 F.3d 364 (7th Cir. 1993) 11

State ex rel. Jones Chemicals, Inc. v. *Seier*, 871 S.W.2d 611 (Mo. Ct. App. 1994) 11

Taylor AG Industries v. *Pure-Gro*, 54 F.3d 555 (9th Cir. 1995) 7, 11, 12

Toy Manufacturers of America v. *Blumenthal*, 986 F.2d 615 (2d Cir. 1993) 21, 22

United States v. *Salerno*, 481 U.S. 739 (1987) 15, 16

TABLE OF AUTHORITIES — Continued

Page

Wallace v. *Parks Corp.*, 629 N.Y.S.2d 570 (N.Y. App. Div. 1995) 11

Worm v. *American Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993) 11, 12

Wright v. *Dow Chemical U.S.A.*, 845 F. Supp. 503 (M.D. Tenn. 1993) 13

Statutes and Regulations:

7 U.S.C. § 136(p)(1) 28

7 U.S.C. § 136(p)(2) 28

7 U.S.C. § 136v 6, 11, 22

15 U.S.C. § 1203 18

15 U.S.C. § 1203(a) 22

15 U.S.C. § 1261 note . . . . . *passim*

15 U.S.C. § 1261(f)(1) 2

15 U.S.C. § 1261(n) 6, 28

15 U.S.C. § 1261(p) 2

15 U.S.C. § 1261(p)(1) 19

15 U.S.C. § 1261(p)(1)(A)-(J) 2

15 U.S.C. § 1261(p)(1)(C) 30

15 U.S.C. § 1261(q) 2

15 U.S.C. § 1262(b) 2, 3

15 U.S.C. § 1269 2

15 U.S.C. § 1278 note 22

15 U.S.C. § 1331-1340 23

15 U.S.C. § 1461 22

TABLE OF AUTHORITIES — Continued

Page

15 U.S.C. § 1476(a) 22
15 U.S.C § 2075(a) 22, 23
15 U.S.C. § 2311(c) 22
15 U.S.C.§ 1203(a) 22
16 C.F.R. §§ 1500.1-.214 21
16 C.F.R. § 1500.3(c)(9) 6
16 C.F.R. § 1500.7 (1974) 28
16 C.F.R. § 1500.7(d) 29
16 C.F.R. § 1500.14(a)(3) 3
16 C.F.R. § 1500.14(b)(3)(ii) 3
16 C.F.R. § 1500.14(b)(3)(iii) 3
21 C.F.R. § 191.4 (1973) 28
21 U.S.C. § 321(k) 28
21 U.S.C. § 321(m) 27
21 U.S.C. § 343-1(a) 22
21 U.S.C. § 360k 16, 29, 23
21 U.S.C. § 360kk(a)(1) 18
21 U.S.C. § 467e 22
21 U.S.C. § 678 22
21 U.S.C. § 1052 22
42 U.S.C. § 6297(a) 22, 23
42 U.S.C. § 6363(e)(1) 23
42 U.S.C. § 14322(e) 23
49 U.S.C. App. § 1305(a)(1) 18

TABLE OF AUTHORITIES — Continued

Page

49 U.S.C. App. § 30103(b) 18

Cal. Code Regs. tit. 22, § 12000 (1996) 4

Cal. Code Regs. tit. 22, § 12601(a) (1996) 4

Cal. Code Regs. tit. 22, § 12601(b)(1) (1996) 4, 6

Cal. Code Regs. tit. 22, § 12601(b)(3) (1996) 4

Cal. Code Regs. tit. 22, § 12601(b)(4)(B) (1996) 4

Cal. Health & Safety Code § 25249.6 (West 1992 & Supp. 1997) 3, 4

Cal. Health & Safety Code § 25249.7 (West 1992 & Supp. 1997) 4

Cal. Health & Safety Code § 25249.10(a) (West 1992 & Supp. 1997) 4

Cal. Health & Safety Code § 25249.11(f) (1992 & Supp. 1997) 10

37 Fed. Reg. 18628 (Sept. 13, 1972) 28

38 Fed. Reg. 27012 (Sept. 27, 1973) 28

47 Fed. Reg. 57489 (Dec. 27, 1982) 29

57 Fed. Reg. 38758 (Aug. 27, 1992) 23

Miscellaneous:

Advisory Op. No. 312 (Mar. 6, 1991) 8, 27

An Act Entitled The "Massachusetts Citizens' Right To Know Act," 1997 MA S.B. 488 (Jan. 1, 1997) 24

H.R. Conf. Rep. No. 1022, 94th Cong., 2d Sess., *reprinted in* 1977 U.S.C.C.A.N. 1030 22

TABLE OF AUTHORITIES — Continued

Page

H.R. Rep. No. 325, 94th Cong., 1st Sess. (1975) 25

Letters Desk, L.A. Times, Sept. 8, 1997 24

Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 ECOLOGY L.Q. 303 (1996) 24

S. Rep. No. 251, 94th Cong., 2d Sess., *reprinted in* 1976 U.S.C.C.A.N. 993 22

PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the California Court of Appeal (App., *infra*, 1a-26a) is reported at 53 Cal. App. 4th 1373, 62 Cal. Rptr. 2d 368. The order of the California Supreme Court denying review (App., *infra*, 27a) is unreported. The trial court's order resolving the cross-motions for summary disposition of the preemption issue (App., *infra*, 28a-29a) is unreported.

JURISDICTION

The California Court of Appeal's judgment was entered on March 31, 1997. The California Supreme Court's order denying review was entered on July 9, 1997. The jurisdiction of this Court is invoked under 28 U.S.C. § 1257(a).

STATUTES AND REGULATIONS INVOLVED

The relevant provisions of the Federal Hazardous Substances Act (15 U.S.C. §§ 1261-1277), the implementing regulations of the Consumer Product Safety Commission (16 C.F.R. § 1500.1 *et seq.*), the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Cal. Health & Safety Code § 25249.5 *et seq.*), and the implementing California regulations (Cal. Code Regs. tit. 22, § 12000 *et seq.*) are set forth at App., *infra*, 41a-47a.

STATEMENT

Through a ballot initiative popularly known as "Proposition 65," California seeks to require manufacturers, distributors and retailers of consumer products that contain hazardous substances to provide particular warnings. The California-required warnings are different from, and in addition to, the warnings and cautionary statements mandated for those products by the Federal Hazardous Substances Act (FHSA) and by the Consumer Product Safety Commission (CPSC), the federal agency that administers the FHSA. The California Attorney General initiated this Proposition 65 enforcement action alleging that petitioner TruServ Corporation (formerly known as Cotter & Company), a member-owned national cooperative, failed to provide the warnings required by Proposition 65 for numerous spray paints, primers, adhesives and other products sold in hundreds of independently owned and operated True Value® Hardware stores in California.

Petitioner maintained that California's warning requirements were expressly preempted by the FHSA, which bars States from imposing any "cautionary labeling requirement" on a hazardous substance that is subject to a federal cautionary labeling requirement that targets the same risk of injury, unless the state and federal requirements are identical. 15 U.S.C. § 1261 note. A California trial court rejected petitioner's preemption defense, and the Court of Appeal affirmed in a lengthy, published opinion.

A. The Statutory And Regulatory Framework.

1. The Federal Hazardous Substances Act And The Federal Toluene Regulation. The FHSA was enacted in 1960 "to 'provide nationally uniform requirements for adequate cautionary labeling of packages of hazardous substances which are sold in interstate commerce and are intended or suitable for household use.'" *Moss* v. *Parks Corp.*, 985 F.2d 736, 739 (4th Cir.) (quoting H.R. Rep. No. 1861, 86th Cong., 2d Sess. 2 (1960)), cert. denied, 509 U.S. 906 (1993); App., *infra*, 15a.[1] Toward that end, the statute imposes detailed and specific requirements concerning the cautionary labeling of all hazardous substances. See 15 U.S.C. § 1261(p)(1)(A)-(J). It also vests the CPSC with comprehensive and exclusive authority to regulate hazardous substances. See 15 U.S.C. §§ 1261(q), 1262(b), 1269.

To ensure the national uniformity of cautionary labeling requirements for hazardous substances, the FHSA provides:

> [I]f a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) [15 U.S.C. §§ 1261(p), 1262(b)] designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in

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[1] The statute defines "hazardous substance" to include any substance that is toxic, corrosive, flammable, combustible, "an irritant," or "a strong sensitizer," or that "generates pressure through decomposition, heat, or other means, if such substance[ ] * * * may cause substantial" injury. 15 U.S.C. § 1261(f)(1)(A). The term also encompasses certain radioactive substances as well as toys and other articles that "present[ ] an electrical, mechanical, or thermal hazard." *Id.* § 1261(f)(1)(C), (D).

> effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under section 2(p) or 3(b).

15 U.S.C. § 1261 note. The statute authorizes the CPSC to grant exemptions from preemption for state requirements that "provide[ ] a significantly higher degree of protection" than the federal requirements, "do[ ] not unduly burden interstate commerce," and (if complied with) "would not cause the hazardous substance" to violate any federal cautionary labeling requirement. *Ibid.*

In addition to mandating the inclusion of certain information and warnings in all hazardous substances labeling, the FHSA authorizes the CPSC to impose additional labeling requirements when, in the agency's judgment, such requirements are "necessary for the protection of the public health and safety." 15 U.S.C. § 1262(b). Exercising that authority, the CPSC has determined that certain additional warnings are required for products "containing * * * 10 percent or more by weight of toluene" (a chemical solvent contained in the products at issue in this litigation). 16 C.F.R. § 1500.14(a)(3). Specifically, the CPSC has determined that such products "shall be labeled with the signal word 'danger,' the statement of hazard 'Harmful or fatal if swallowed,' and the statement 'Call physician immediately.'" *Id.* § 1500.14(b)(3)(ii). In addition, because the "inhalation of the vapor of products containing 10 percent or more by weight of toluene * * * may cause systemic injury, such products shall bear the statement of hazard 'Vapor harmful'" as well. *Id.* § 1500.14(b)(3) (iii).

2. Proposition 65. In 1986, the voters of California approved Proposition 65, formally known as the "California Safe Drinking Water and Toxic Enforcement Act of 1986." Proposition 65 establishes the following warning requirement:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual * * *.

Cal. Health & Safety Code § 25249.6 (West 1992 & Supp. 1997). Violations of Section 25249.6 "may be enjoined" and are subject to "a civil penalty not to exceed $2500 per day." *Id.* § 25249.7(a), (b). Proposition 65 authorizes enforcement actions not only by the California Attorney General and certain other state and local authorities but also "by any person in the public interest," if the private enforcement action is commenced "more than sixty days" after notice is provided to the "alleged violator" and to state officials, and the latter decline to "commence[ ] and diligently prosecute an action." *Id.* § 25249.7(c), (d). Proposition 65 contains an exemption from the warning requirement for "[a]ny exposure for which federal law governs warning in a manner that preempts state authority." *Id.* § 25249.10(a).

On January 1, 1992, one year after the State of California classified toluene as a reproductive toxin (Cal. Code Regs. tit. 22, § 12000 (1996)), the warnings required under Proposition 65 became effective for the chemical. App., *infra*, 2a n.3. Thereafter, consumer products containing toluene were required by California law to be accompanied by warnings that "clearly communicate that the chemical in question is known to the state to cause * * * birth defects or other reproductive harms." Cal. Code Regs. tit. 22, § 12601(a) (1996); see also *id.* § 12601(b)(1)(A)-(B), 12601(b)(3), (b)(4)(B) (compliance with Proposition 65 may be ensured by providing the following statement either "prominently placed" in the product labeling or "conspicuous[ly]" displayed in a "sign" at the retail outlet: "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.").

B. The Proceedings Below.

1. The Trial Proceedings. After a nonprofit organization called "As You Sow" alleged that petitioner had failed to provide adequate warnings of toluene exposure in violation of Proposition 65, the California Attorney General filed this lawsuit in the state superior court. App., *infra*, 2a-3a; California Court of Appeal Joint Appendix (C.A. App.) 1-9. As You Sow subsequently intervened. App., *infra*, 25a n.23.

Petitioner raised the defense of preemption in its answer. C.A. App. 11, 384. Petitioner subsequently moved for summary

judgment on the ground that the Proposition 65 claims were preempted by the FHSA. C.A. App. 430-454. Those claims, petitioner argued, rested on the premise that the federally required labeling of products containing toluene was inadequate, and sought, impermissibly, to impose a different state "cautionary labeling requirement" on these products. The State filed a cross-motion for summary adjudication, which As You Sow joined. C.A. App. 743-778, 1665-1668. Relying principally on *Chemical Specialties Mfrs. Ass'n, Inc.* v. *Allenby*, 958 F.2d 941 (9th Cir.), cert. denied, 506 U.S. 825 (1992), the superior court granted respondents' motion for summary adjudication and denied petitioner's motion for summary judgment. App., *infra*, 28a-29a.

Petitioner then entered into a consent judgment requiring it to pay $275,000 in penalties and restitution for the Proposition 65 violations, but preserving petitioner's right to appeal from the preemption ruling. App., *infra*, 3a, 32a-33a, 36a-37a.[2]

2. The Court Of Appeal's Decision. The California Court of Appeal, First Appellate District, affirmed the superior court's preemption ruling in a lengthy opinion. App., *infra*, 1a-26a.

The Court of Appeal characterized petitioner's preemption defense to this enforcement action as raising a "facial challenge to Proposition 65," which, to succeed, "must establish [that] Proposition 65 would not be valid under *any* set of circumstances." App., *infra*, 5a (citing *Allenby*) (emphasis added). Next, the Court of Appeal "review[ed] the federal preemption doctrine" and summarized this Court's decisions in *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), and *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992). App., *infra*, 6a, 8a-10a. The court purported to derive two principles from *Medtronic*. First, "a decision regarding preemption should consider the 'generality' of the federal statute" because, if federal requirements are general, they are unlikely to be preemptive. App, *infra*, 10a. Second, "courts should broadly interpret the preemption provision of federal statutes with

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[2] To avoid the accumulation of daily penalties under Proposition 65, petitioner also agreed, in 1994, to the entry of a permanent injunction governing the provision of future warnings. See App., *infra*, 33a, 37a. That order is not at issue in this case.

limited applicability and narrowly interpret those statutes with general applicability." *Id.* at 9a.

The Court of Appeal next examined the pre-*Cipollone* decision in *Allenby*, which held that Proposition 65 was not facially invalid under either the FHSA or the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136v. The Ninth Circuit had rested its conclusion on California regulations that implement Proposition 65, which recognize "four types of 'safe harbor' warnings for consumer products": "product labeling, 'shelf labeling, signs, menus, or a combination thereof.'" App., *infra*, 4a, 11a-12a (quoting Cal. Code Regs. tit. 22, § 12601(b)(1)(B)). The FHSA's preemption of certain state "cautionary labeling requirement[s]," the Ninth Circuit reasoned, does not extend to state-mandated warnings in materials other than the product "label."[3] Because a retailer may comply with Proposition 65 by providing warnings in point-of-sale signs, and because such signs do not qualify as "labels" as that term is defined in the FHSA, the *Allenby* court concluded, the requisite showing for a facial challenge cannot be made. 958 F.2d at 943, 949-50.

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[3] In concluding that a point-of-sale sign does not qualify as a "label" under the FHSA, the *Allenby* court relied on the following definition:

> The term "label" means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the case of an article which is unpackaged * * * , a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (1) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (2) on all *accompanying literature* where there are *directions for use*, written or otherwise.

15 U.S.C. § 1261(n) (emphasis added). The CPSC's regulations define "accompanying literature" to include point-of-sale signs. See 16 C.F.R. § 1500.3(c)(9).

The California Court of Appeal adopted the analysis of *Allenby* and held that "the preemption provision in the FHSA only applies to 'cautionary labels' on packages." App., *infra*, 11a. It rejected the argument that *Cipollone*, by holding that "the central inquiry for preemption is whether the state and federal statutes have the same predicate duty," had undermined *Allenby*'s rationale. *Id.* at 12a. According to the Court of Appeal, *Medtronic* established that *Cipollone*'s framework for analysis "does not apply when both the federal and state statutes require a *general* warning for a variety of products and do not target *specific* products." App., *infra*, 13a (emphasis added).

The Court of Appeal also expressly endorsed "*Allenby*'s analysis of labels under the FHSA." App., *infra*, 14a. In interpreting the FHSA's definition of "label" and of the phrase "accompanying literature where there are directions for use" (see note 3, *supra*), the Court of Appeal stated that, "[f]ollowing *Medtronic*, we must interpret the words in the preemption statute narrowly when the federal statute and state statute have general applicability." App., *infra*, 15a. Because the FHSA "is an extremely broad statute," the Court of Appeal opined, it must be narrowly interpreted under *Medtronic*. *Id.* at 16a. The Court of Appeal nevertheless agreed with petitioner that the warnings required by Proposition 65 in this case target the same risk as the warnings mandated under the FHSA. *Id.* at 16a-17a n.13.

The Court of Appeal acknowledged that the language of FIFRA's preemption provision is "essentially identical" to FHSA's preemption provision and that "numerous FIFRA cases" — including *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555 (9th Cir. 1995) — have held that "FIFRA preempt[s] common law claims based on inadequate point of sale warnings." App., *infra*, 17a. Nevertheless, the court concluded that those FIFRA cases were distinguishable, expressly disagreeing with the Ninth Circuit's conclusion in *Allenby* that "the issue of preemption arising under FIFRA is identical to that under the FHSA." *Id.* at 19a n.16.

The Court of Appeal also acknowledged that common law damages actions "pose the same questions and issues" in determining the "scope of preemption" as do cases involving enforcement actions. Nevertheless, the court sought to distinguish

the FIFRA cases precisely because many of them involved common law claims, asserting that the "analyses of tort and enforcement actions diverge in a materially significant respect" once "the preempted domain" is determined. App., *infra*, 20a. The court elaborated (*ibid.*):

> Once the court determines a common law claim falls within the reach of the preemption clause, the analysis ceases. The federal government's interest in promoting interstate commerce always trumps the individual's interest in receiving damages.
>
> Unlike a tort action, an enforcement action requires the court to establish whether any method of compliance with the state statute falls outside the scope of the preemption provision. If any method is beyond the reach of the preemption provision, the statute remains valid.

Thus, the court concluded, "an enforcement action *never* requires the court to assess the adequacy of the label, while that is the task facing the court in a tort action." *Id.* at 21a (emphasis added).

Finally, the Court of Appeal rejected petitioner's argument that it should reconsider and reject *Allenby*'s interpretation of the phrase "directions for use" because the CPSC General Counsel, in an advisory opinion, has interpreted the phrase more broadly to include warnings in point-of-sale signs such as those required under Proposition 65. App., *infra*, 21a-22a. Under the agency's interpretation, a warning that a product can cause cancer or birth defects "'can also serve as a direction for use'" because it "'conveys the information that, in using the product, steps should be taken to minimize or eliminate exposure.'" *Id.* at 21a (quoting Advisory Op. No. 312, at 3 (Mar. 6, 1991)). The Court of Appeal refused to defer to this agency interpretation, however, on the ground that it was "plainly erroneous and entitled to no deference." *Id.* at 22a (internal quotations omitted).

On July 9, 1997, the California Supreme Court denied petitioner's request for review. App., *infra*, 29a.

REASONS FOR GRANTING THE PETITION

This case presents the Court with an opportunity to resolve a number of significant issues as to which the lower courts are in conflict concerning the preemptive scope of the FHSA, an important federal statute that applies to thousands of consumer products. Because more than a dozen other federal preemption provisions mirror the FHSA in barring the imposition of state "labeling" requirements, this Court's review would also go far in clarifying the law and resolving various conflicts under those statutes. And this case is an ideal vehicle for the Court to bring greater clarity generally to the law of federal preemption, which in recent years has spawned substantial litigation as courts have struggled to interpret and apply *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240 (1996), and *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992). With its heavy reliance on a host of secondary and tertiary rules of interpretation (rather than on a straightforward examination of the text and structure of the FHSA's preemption provision), the lower court's opinion provides a compelling illustration of the need for greater guidance and clarification from this Court.

I. THE DECISION BELOW CONFLICTS IN MULTIPLE RESPECTS WITH THE DECISIONS OF OTHER COURTS

A. Courts Are Deeply Divided Over Whether FHSA And Other Federal Statutes That Expressly Preempt State "Labeling" Requirements Nevertheless Permit States To Require Warnings Outside The Product "Label"

Warnings can be communicated on a product's label, in point-of-sale signs, or in many other ways. If federal law requires a warning on the product's "label," and state law requires some other warning *outside* of the "label," the necessary premise of the state law is that the federally mandated warnings are inadequate. See, *e.g.*, *Papas* v. *Upjohn Co.*, 985 F.2d 516, 519 (11th Cir.) ("any claims that point-of-sale signs, consumer notices, or other informational materials failed adequately to warn the plaintiff *necessarily challenge the adequacy of the warnings provided on the product's labeling or packaging*") (emphasis added), cert. denied, 510 U.S. 913 (1993). Nevertheless, paying more attention to the placement of the required warning than to the State's reason for

requiring that warning, the Court of Appeal concluded that the FHSA's express preemption of state "cautionary labeling requirement[s]" does not include cautionary warnings that are required to be communicated outside of the "label." The Court of Appeal's reasoning cannot be squared with a long line of decisions involving preemption under the FHSA and other federal statutes that preempt state "labeling" requirements.

Federal and state courts have held that failure-to-warn claims brought under state tort law are preempted by the FHSA. The common law "duty to warn" invoked by such claims — and held to be preempted — is not a duty to warn through a particular *means* of communication; the defendant could discharge its duty by providing warnings *outside the product label*, such as in point-of-sale signs or through face-to-face communication.[4] Nevertheless, courts have repeatedly concluded that failure-to-warn claims are entirely preempted — despite the urging of some plaintiffs to hold them preempted only insofar as they would require additional warnings in product labels.

For example, in *Comeaux* v. *National Tea Co.*, 81 F.3d 42 (1996), the Fifth Circuit concluded that a failure-to-warn claim brought under Louisiana law against the manufacturer of lighter fluid was preempted by the FHSA, because the FHSA and its implementing regulations imposed labeling requirements on the product. "The FHSA," the Fifth Circuit categorically declared, "preempts *any* state law warning requirements other than those imposed by the FHSA and its implementing regulations." *Id.* at 43 (emphasis added); see also *id.* at 44 (stating that FHSA preempts "any other or further warnings requirements").

Similarly, the Fourth Circuit has concluded that a "common law tort action based upon failure to warn may only be brought for non-compliance with existing federal labeling requirements"

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[4] Proposition 65 mirrors the common law duty to warn by stating that warnings "may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." Cal. Health & Safety Code § 25249.11(f) (West 1992 & Supp. 1997).

imposed under FHSA. *Moss* v. *Parks Corp.*, 985 F.2d 736, 740 (4th Cir.), cert. denied, 509 U.S. 906 (1993). Other courts have also concluded that the FHSA preempts failure-to-warn claims.[5]

Federal and state courts have reached the same conclusion in cases involving preemption of failure-to-warn claims under FIFRA. As the California Court of Appeal acknowledged, the language of FIFRA's preemption clause "is essentially identical" to the FHSA's. App., *infra*, 17a. Like the FHSA preemption provision, the FIFRA preemption clause reaches all state "requirements *for labeling* or packaging" that are not identical to "those required" under FIFRA. 7 U.S.C. § 136v (emphasis added). Almost without exception, the federal courts of appeals have held that state tort claims for failure to warn are preempted even where such warnings could be communicated through means other than the product labeling — including through point-of-sale signs.[6]

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[5] See, *e.g.*, *Lee* v. *Boyle-Midway Household Prods., Inc.*, 792 F. Supp. 1001, 1007-09 (W.D. Pa. 1992); *Salazar* v. *Whink Prods. Co.*, 881 P.2d 431 (Colo. Ct. App. 1994), cert. denied, 514 U.S. 1004 (1995); *Busch* v. *Graphic Color Corp.*, 662 N.E.2d 397, 405-06 (Ill.), cert. denied, 117 S. Ct. 55 (1996); *State ex rel. Jones Chemicals, Inc.* v. *Seier*, 871 S.W. 2d 611 (Mo. Ct. App. 1994); *Canty* v. *Ever-Last Supply Co.*, 685 A.2d 1365, 1374-75 (N.J. Super. Ct. 1996); *Beyrle* v. *Finneron*, 645 N.Y.S.2d 192, 193 (N.Y. App. Div. 1996); *Wallace* v. *Parks Corp.*, 629 N.Y.S.2d 570, 573-74 (N.Y. App. Div. 1995); *Jenkins* v. *James B. Day & Co.*, 634 N.E.2d 998 (Ohio 1994). But see *Duplin* v. *Whink Prods. Co.*, 1994 WL 197612 (Conn. Super. Ct. May 2, 1994).

[6] See *King* v. *E.I. Dupont De Nemours & Co.*, 996 F.2d 1346, 1349-50 (1st Cir.), cert. dismissed, 510 U.S. 985 (1993); *Worm* v. *American Cyanamid Co.*, 5 F.3d 744, 748 (4th Cir. 1993); *MacDonald* v. *Monsanto Co.*, 27 F.3d 1021, 1024-25 (5th Cir. 1994); *Shaw* v. *Dow Brands, Inc.*, 994 F.2d 364, 369-71 & n.4 (7th Cir. 1993); *Bice* v. *Leslie's Poolmart, Inc.*, 39 F.3d 887, 888 (8th Cir. 1994); *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995); *Arkansas-Platte & Gulf Partnership* v. *Van Waters & Rogers, Inc.*, 981 F.2d 1177 (10th Cir.), cert. denied, 510 U.S. 813 (1993); *Papas*, 985 F.2d at 519. But see *Ferebee* v. *Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir.), cert. denied, 469 U.S. 1062 (1984).

Many of these federal decisions specifically mention point-of-sale signs as an alternative method of satisfying the duty to warn and reject the argument that such signs are not preempted by FIFRA. For example, the Eleventh Circuit in *Papas* stated:

> Appellants * * * contend that because the language of 136v refers only to "labeling or packaging," the section does not pre-empt failure to warn claims based on *point-of-sale signs, consumer notices, or other informational materials that are "unrelated" to labeling and packaging*. * * * If a pesticide manufacturer places EPA-approved warnings on the label and packaging of its product, its duty to warn is satisfied, and the adequate warning issue ends. Plaintiffs may not interfere with the FIFRA scheme by bringing a common law action alleging the inadequacy of, for example, point-of-sale signs.

985 F.2d at 519 (emphasis added). The Fourth and Ninth Circuits and the Supreme Courts of Washington and Kansas have reached exactly the same conclusion. See *Worm* v. *American Cyanamid Co.*, 5 F.3d 744, 748 (4th Cir. 1993); *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995); *Goodwin* v. *Bacon*, 896 P.2d 673, 681 (Wash. 1995); *Jenkins* v. *Amchem Prods., Inc.*, 886 P.2d 869, 881-82 (Kan. 1994), cert. denied, 116 S. Ct. 80 (1995).

These decisions rest on the sensible notion that any "claim for inadequate point-of-sale warnings" is "premised ultimately upon the inadequacy of the product label." *Taylor*, 54 F.3d at 561. Accord *Papas*, 985 F.2d at 519; *Worm*, 5 F.3d at 748; *Lowe* v. *Sporicidin Int'l*, 47 F.3d 124, 129-30 (4th Cir. 1995). In contrast, a minority of federal and state courts have concluded, as did the Court of Appeal in this case, that a state-imposed obligation to provide warnings is not preempted as a "labeling" requirement unless it mandates the inclusion of warnings *in the product's "label."* For example, the Second Circuit, in *New York State Pesticide Coalition, Inc.* v. *Jorling*, 874 F.2d 115 (1989), held that FIFRA preempts only state requirements in "labeling" or "packaging" and that these terms do not include signs aimed at providing information to the general public. *Id.* at 118-20.[7]

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[7] See also *Burke* v. *Dow Chem. Co.*, 797 F. Supp. 1128, 1140

Tellingly, both lines of cases purport to derive support from *Cipollone*. For example, the Eleventh Circuit in *Papas* (985 F.2d at 518-19) relied on Justice Stevens' plurality opinion in *Cipollone*, which concluded that the plaintiffs' failure to warn claims were preempted "insofar as [they] * * * require a showing that respondents' post-1969 advertising or promotions should have included additional, or more clearly stated, warnings." 505 U.S. at 524. On the other hand, the district court in *Burke* v. *Dow Chem. Co.*, 797 F. Supp. 1128, 1138, 1140-41 (E.D.N.Y. 1992), took note of the *Cipollone* plurality's refusal to find plaintiffs' fraudulent concealment claims preempted "insofar as those claims rely on a state-law duty to disclose such facts through channels of communication other than advertising or promotion." 505 U.S. at 528. Only this Court can definitively reconcile the statements that have led the lower courts into conflict.

The sharp conflict between these two lines of FIFRA decisions has been widely noted.[8] To resolve this far-reaching conflict over the scope of preemption effected by federal statutes that displace state "labeling requirements," further review by this Court is needed.

(E.D.N.Y. 1992); *D-Con Co.* v. *Allenby*, 728 F. Supp. 605, 607 (N.D. Cal. 1989) ("[m]any warning methods, including the point-of-sale signs currently designated a 'safe harbor' under Prop 65, may satisfy the requirements of the state of California without infringing on federal supremacy in the area of pesticide labeling"); *Malone* v. *American Cyanamid Co.*, 649 N.E.2d 493, 498-99 (Ill. Ct. App.), appeal denied, 657 N.E.2d 624 (Ill. 1995); *Macrie* v. *SDS Biotech Corp.*, 630 A.2d 805, 812-13 (N.J. Super. A.D.), cert. denied, 636 A.2d 522 (N.J. 1993).

[8] See, *e.g.*, *Kuiper* v. *American Cyanamid Co.*, 913 F. Supp. 1236, 1239-45 (E.D. Wis. 1996) (reviewing conflict and expressly disagreeing with *Burke* and *Malone*); *Wright* v. *Dow Chem. U.S.A.*, 845 F. Supp. 503, 508 n.2, 510 (M.D. Tenn. 1993) (disagreeing with *Burke*); *DerGazarian* v. *Dow Chemical Co.*, 836 F. Supp. 1429, 1433-47 & nn.1-2 (W.D. Ark. 1993) (extensively reviewing the "split of authority"); *Goodwin*, 896 P.2d at 681 (noting conflict and agreeing with "the majority of courts" that have "refus[ed] to distinguish non-label failure to warn"); *Jenkins*, 886 P.2d at 881-82 (same).

B. The Court Of Appeal's Conclusions That FHSA And FIFRA Preemption Are Not Coextensive, And That Preemption Cases Involving Common Law Claims Are Immaterial To Enforcement Actions, Conflict With The Decisions Of Other Courts

The Court of Appeal's holding rested substantially on its conclusion that cases involving FIFRA preemption — including "numerous * * * cases which found [that] FIFRA preempt[s] common law claims based on inadequate point of sale warnings" — are not controlling. App., *infra*, 17a-21a. In addition, the Court of Appeal reasoned that cases involving the preemption of state *common law requirements* are not relevant to cases involving the preemption of a state *statutory requirements*. These conclusions cannot be reconciled with this Court's decisions in *Cipollone* and *Medtronic* or with the decisions of other state and federal courts.

Most courts that have the considered the relationship between FIFRA and FHSA preemption have concluded, contrary to the decision below, that they are coextensive. In *Allenby* the Ninth Circuit stated unequivocally that "[t]he preemption issues arising under FHSA are identical to those arising under FIFRA." 958 F.2d at 945. The Fourth and Fifth Circuits have reached the same conclusion. See *Moss*, 985 F.2d at 740 n.3; *Comeaux*, 81 F.3d at 44. The Illinois Supreme Court has stated that FIFRA's preemption provision "is substantially equivalent * * * to the FHSA's preemption provision." *Busch* v. *Graphic Color Corp.*, 662 N.E.2d 397, 405 (Ill.), cert. denied, 117 S. Ct. 55 (1996); accord *Wallace* v. *Parks Corp.*, 629 N.Y.S.2d 570, 573 (N.Y. App. Div. 1995).

The Court of Appeal acknowledged this conflict by stating that it "disagreed" with *Allenby* on this point. App. *infra*, 19a n.16. This conflict is all the more troubling because California is located within the Ninth Circuit. This Court has repeatedly granted review to resolve conflicts between a state appellate court and the federal circuit in which it is situated, in order to prevent forum-shopping. See *Baldwin* v. *Alabama*, 472 U.S. 372, 374 (1985).

The Court of Appeal's *reasons* for refusing to apply the numerous FIFRA cases discussed above, moreover, conflict with this Court's decisions in *Cipollone* and *Medtronic*. In the lower court's

view, these FIFRA cases are inapposite because they are "predominantly tort common law cases and this is a Proposition 65 enforcement action." App., *infra*, 17a. Damages actions are more easily preempted, the court explained, because "[o]nce the court determines a common law claim falls within the reach of the preemption clause * * * [t]he federal government's interest in promoting interstate commerce *always* trumps the individual's interest in receiving damages." *Id.* at 20a (emphasis added).

That analysis, however, is fundamentally incompatible with this Court's teachings. In *Cipollone* and again in *Medtronic*, a majority of this Court pointedly refused to distinguish for preemption purposes between the "requirements" imposed by state common law and state statutes (or other positive law). See *Medtronic*, 116 S. Ct. at 2259 (opinion of Breyer, J.); *id.* at 2262-63 (O'Connor, J., joined by Rehnquist, C.J., & Scalia & Thomas, JJ., concurring in part and dissenting in part); *Cipollone*, 505 U.S. at 521 (plurality); *id.* at 548-49 (Scalia, J., joined by Thomas, J., concurring in part and dissenting in part). See also *MacDonald* v. *Monsanto*, 27 F.3d 1021, 1024 (5th Cir. 1994). The *Cipollone* plurality stated that the "[t]he phrase 'no requirements or prohibition'" in the federal Cigarette and Labeling and Advertising Act "sweeps broadly and suggests *no distinction* between positive enactments and common law." 505 U.S. at 521 (emphasis added). Even the three Justices who disagreed with this conclusion in *Cipollone* suggested that common law requirements should be given *more*, not *less*, solicitude in any preemption analysis. See *id.* at 534-44 (separate opinion of Blackmun, J., joined by Kennedy & Souter, JJ.).

Even more troubling is the Court of Appeal's related suggestion that cases involving common law claims are distinguishable from enforcement actions because "an enforcement action," unlike a tort action, "requires the court to establish whether *any* method of compliance with the state statute falls outside the scope of the preemption provision." App., *infra*, 20a (emphasis added). The two cases cited for that proposition do not support it; both involved *declaratory judgment actions* seeking a determination that state statutes were *facially invalid*. Therefore, both applied the stringent standard articulated in *United States* v. *Salerno*, 481 U.S. 739, 745 (1987): "A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger

must establish that no set of circumstances exists under which the Act would be valid." See *Allenby*, 958 F.2d at 943. Compare *Industrial Truck Ass'n* v. *Henry*, 1997 WL 594619, at *11-*12 (9th Cir. Sept. 29, 1997) (holding, in declaratory judgment action, that Proposition 65 warning requirements are preempted by OSHA "as applied to manufacturers and distributors of industrial trucks").

The Court of Appeal's adoption of the *Salerno* standard for all preemption cases involving the enforcement of state statutes marks a radical — and radically misguided — departure from this Court's preemption cases. See, *e.g.*, *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992) (analyzing whether state enforcement actions are preempted without any hint that facial challenge standard governs). It also makes utterly no sense. In defending against this enforcement action, petitioner never undertook (nor had any need to undertake) to show that Proposition 65 was preempted by the FHSA in every conceivable application. On the contrary, as petitioner's answer makes clear, petitioner sought only to make the more limited showing that the FHSA "preempt[s] the application of Proposition 65 * * * to [petitioner's] products." C.A. App. 11. The *Salerno* standard does not govern that inquiry.

C. The Decision Below Conflicts With Those Of Other Courts Concerning The Applicability Of *Medtronic's* "General/Specific" Distinction Outside Of The Context Of Preemption Under The Medical Device Amendments

The Court of Appeal relied substantially for its holding on *Medtronic*, which construed the express preemption provision of a different statute — the Medical Device Amendments (MDA) to the federal Food, Drug & Cosmetic Act, 21 U.S.C. § 360k. The Court of Appeal interpreted *Medtronic* as altering the basic principles governing preemption analysis (including those set forth in this Court's decision in *Cipollone*) whenever "both the federal and state statutes" at issue "require a *general* warning for a variety of products and do not target *specific* products." App., *infra*, 13a (emphasis added). Applying the "general/specific" distinction it perceived in *Medtronic*, the Court of Appeal concluded that there was no preemption because both the FHSA and Proposition 65 are "general" in nature. *Ibid.*

The Court of Appeal's holding is squarely at odds with the decisions of other federal and state courts. Other courts have concluded that the analytical framework of *Medtronic* (including the "general/specific" distinction) hinged on the unique language of the MDA and, more important, on the interpretation given to the statutory text by the agency charged with administering the statute, the Food and Drug Administration (FDA). Accordingly, many courts have *rejected* the argument that *Medtronic* alters the basic principles governing preemption law and have *refused* to apply *Medtronic*'s "general/specific" distinction outside the MDA context.[9]

Illustrative is *Ackles* v. *Luttrell*, 561 N.W.2d 573 (Neb. 1997), pet. for cert. filed, 66 U.S.L.W. 3137 (Aug. 6, 1997) (No. 97-226). There, the Nebraska Supreme Court rejected the argument that *Medtronic* was applicable to a case involving preemption under FIFRA. "[W]hile at first blush *Medtronic* * * * appears to retreat from * * * *Cipollone*," the court explained, "it was the separate and distinct statutes that were involved in each case that were the determining factor." 561 N.W.2d at 578. Concluding that FIFRA's preemption provision was dissimilar to the statute involved in *Medtronic*, the Nebraska Supreme Court refused to fol-

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[9] There is also considerable confusion in the lower courts about whether this Court's holding in *Medtronic* rests on the generality of the state (as opposed to the federal) requirements at issue in that case. As the Court of Appeal correctly noted (App., *infra*, 13a), the Ninth Circuit has concluded, in another MDA preemption case, that Proposition 65 is a state law of "general applicability" and thus exempt from MDA preemption under *Medtronic*. See *Committee of Dental Amalgam Mfrs. & Distribs.* v. *Stratton*, 92 F.3d 807, 813 (9th Cir. 1996), cert. denied, 117 S. Ct. 754 (1997). But the Ninth Circuit later repudiated the suggestion in *Stratton* that the outcome in *Medtronic* depended in part on the absence of specificity in the pertinent state requirements. See *Papike* v. *Tambrands Inc.*, 107 F.3d 737, 742 (1997), pet. for cert. filed, 66 U.S.L.W. 3107 (July 15, 1997) (No. 97-94); *Harris* v. *Ford Motor Co.*, 110 F.3d 1410, 1414 n.8 (9th Cir. 1997) ("We do not believe that *Medtronic* precludes express pre-emption when a *state law of general applicability* (like tort law) is involved.") (emphasis added). Other circuits have reached the same conclusion. See *Mitchell* v. *Collagen Corp.*, 1997 WL 584550, at *6 (7th Cir. Sept. 23, 1997). But see *Oja* v. *Howmedica Inc.*, 111 F.3d 782, 788-89 (10th Cir. 1997).

low the framework announced in *Medtronic*. Other courts have reached conflicting results over whether the reasoning of *Medtronic* applies to express preemption under statutes other than the MDA.[10]

The Court of Appeal's use of the "general/specific" distinction as a basis for limiting FHSA preemption is also in significant tension with several pre-*Medtronic* cases in which this Court categorically rejected arguments for similar limitations. For example, in *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992), the Court interpreted a provision of the Airline Deregulation Act of 1978 (ADA) that "pre-empts the States from 'enact[ing] or enforc[ing] any law, rule, regulation, standard or other provision * * * relating to rates, routes, or services of any air carrier.'" *Id.* at 383 (quoting 49 U.S.C. App. § 1305(a)(1)). The Court flatly rejected the argument that "only state laws specifically addressed to the airline industry are preempted, whereas the ADA imposes no constraints on laws of general applicability." *Id.* at 386. Such an interpretation, this Court noted, would create "an utterly irrational loophole." *Ibid.* The Court has rejected the same argument in other preemption cases. See, *e.g.*, *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 47-48 (1987) (ERISA preemption is not limited to state measures targeting ERISA plans); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 244 & n.3 (1959)

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[10] Compare *Industrial Truck Ass'n.* v. *Henry*, 1997 WL 594619, at *4-*12 (9th Cir. Sept. 29, 1997) (holding that Proposition 65 warning requirements are preempted by OSHA without mention of "general/specific" framework), *Brand* v. *Mazda Motor Corp.*, 1997 WL 109976, at *3 (D. Kan. Feb. 12, 1997) (rejecting argument *Medtronic* "impliedly overruled" prior cases relating to preemption under the National Traffic and Motor Vehicle Safety Act, 49 U.S.C. § 30103(b)), and *Lewis* v. *American Cyanamid Co.*, 682 A.2d 724, 730-32 (N.J. Super. Ct. App. Div. 1996) (refusing to apply *Medtronic* to preemption under FIFRA), cert. granted, 697 A.2d 546 (N.J. 1997), with *Harris*, 110 F.3d at 1414 & n.7 (stating that "*Medtronic*'s generality/specificity analysis * * * informs our analysis" of express preemption issues under the National Traffic and Motor Vehicle Safety Act), and *Askenazi* v. *Hymil Mfg. Co.*, 648 N.Y.S.2d 895, 897-98 (N.Y. Sup. Ct. 1996) (applying *Medtronic* to preemption under the Flammable Fabrics Act, 15 U.S.C. § 1203).

(NLRA preemption not limited to state laws "specifically directed towards the governance of industrial relations."). *Medtronic* did not disavow this unbroken line of cases relating to preemption provisions other than that of the MDA.[11]

What is more, the Illinois Supreme Court, in a case decided before *Medtronic*, has squarely rejected the argument that labeling requirements imposed by the FHSA do not give rise to preemption if they "set forth no specific precautions for any specific type of product." *Busch* v. *Graphic Color Corp.*, 662 N.E.2d 397, 406 (Ill.), cert. denied, 117 S. Ct. 55 (1996). The court explained:

> Despite the fact that the provisions are couched in general terms encompassing every type of hazardous substance, they are nonetheless requirements for the cautionary labeling of hazardous substances * * *.

Ibid.; see 15 U.S.C. § 1261(p)(1). The Illinois Supreme Court accordingly concluded that the FHSA-imposed labeling requirements trigger preemption even if they are general in nature and apply to a variety of hazardous substances. That conclusion is squarely at odds with the Court of Appeal's holding in this case.

Not only did the Court of Appeal erroneously apply *Medtronic*'s "general/specific" distinction to the FHSA, it applied a distorted version of that distinction. The lower court declared that under *Medtronic* "courts should broadly interpret the preemption provision of federal statutes with limited applicability and narrowly interpret those statutes with general applicability."

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[11] In *Schuver* v. *E.I. du Pont de Nemours & Co.*, 117 S. Ct. 274 (1996), this Court refused to grant, vacate, and remand for reconsideration in light of *Medtronic* a decision of the Iowa Supreme Court holding that FIFRA preempted certain tort claims brought under state law. The petitioner (who was represented by the same lawyers who handled *Medtronic* for the plaintiffs) unsuccessfully argued that *Medtronic*'s "general/specific" distinction was equally applicable to FIFRA's preemption provision. No. 96-68 Pet. for Cert. 13-14 (filed July 12, 1996). Compare *Papas* v. *Zoecon Corp.*, 505 U.S. 1215 (1992) (granting, vacating and remanding FIFRA case in light of *Cipollone*); *Arkansas-Platte & Gulf Partners* v. *Dow Chem. Co.*, 506 U.S. 910 (1992) (same).

App., *infra*, 9a.[12] But the generality and specificity at issue in *Medtronic* was that of the pertinent state and federal *requirements*, not of the *statutes* as a whole (or even of the *preemption provisions*).

As if that were not enough, the Court of Appeal's interpretive maxim *conflicts* with the majority's position in *Medtronic*. The Court of Appeal evidently derived its canon from Justice Stevens's effort to explain, *on behalf of only four Members of the Court*, why the word "requirement" in the MDA's preemption provision should not be read in precisely the same way as the word "requirement" in the different preemption provision at issue in *Cipollone*. See *Medtronic*, 116 S. Ct. at 2251-52 (plurality). But the other five Justices expressly *disagreed with* Justice Stevens's attempt to distinguish *Cipollone* on that basis. See *id.* at 2262-63 (opinion of O'Connor, J.); *id.* at 2259, 2261-62 (opinion of Breyer, J.).

The Court of Appeal's pervasive confusion stems from its difficulty in understanding and applying this Court's complex, fragmented decisions in *Cipollone* and *Medtronic*. Both of those decisions were rendered by sharply divided Courts, with holdings emerging only from the shifting overlap of multiple opinions. As we previously noted (at page 13), divergent interpretations of *Cipollone* have contributed to conflicts in how the lower courts have interpreted statutes like the FHSA. And, in the case of *Medtronic*, the federal courts of appeals have correctly identified a number of important ambiguities. See *Mitchell* v. *Collagen*, 1997 WL 584550, at *7 (7th Cir. Sept. 23, 1997) (stating that

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[12] A rule of narrow construction is especially inappropriate in this case because (1) in contrast to the preemption provision at issue in *Medtronic*, the FHSA's preemption provision, which applies only to nonidentical state "cautionary labeling requirements" and only then to state requirements that target the same risk as the federal requirements, is already relatively limited in scope; (2) Congress has included an exemption procedure under which States may obtain permission from the CPSC to avoid preemption, thus removing the primary rationale for the rule of narrow construction (namely, that a "State can do nothing" if preemption is erroneously found, see *Allenby*, 958 F.2d at 943); and (3) Proposition 65 itself envisions that certain of its requirements will be preempted by federal law. See pages 2-4, *supra*.

Medtronic "contains several ambiguities" and "presents a difficult situation for an intermediate appellate court"); *Grenier* v. *Vermont Log Bldgs., Inc.*, 96 F.3d 559, 564 (1st Cir. 1996) ("[T]he signals from the Supreme Court are blurred by disagreements within the Court."). To clarify the ambiguities in *Medtronic* and *Cipollone*, and to provide more guidance to businesses and consumers in the important area of preemption law, further review is warranted.[13]

II. THE ISSUES PRESENTED ARE RECURRING AND OF ENORMOUS PUBLIC IMPORTANCE

The issues raised by this case arise with regularity and are vitally important to the proper administration of federal law.

Even if this case were solely about the scope of preemption under the FHSA, it would merit this Court's attention. The FHSA applies to a wide range of hazardous substances, toys, and other articles intended for use by children. See note 1, *supra*. Many of these individual substances, moreover, are contained in a broad range of consumer products. In 1960, when the FHSA was enacted, proponents of the legislation expected that it would "improve warnings on the labels of over 300,000 common household products." *Burch* v. *Amsterdam Corp.*, 366 A.2d 1079, 1085 (D.C. 1976). Today, the CPSC's regulations mandate additional specific warnings for scores of hazardous substances. See generally 16 C.F.R. §§ 1500.1-.214 (1997).

In view of the FHSA's widespread applicability, it comes as no surprise that issues of preemption under the FHSA arise frequently in the federal and state courts. See cases cited at pages 10-11, 14 & notes 5-6, *supra*. See also, *e.g.*, *Hunnings* v.

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[13] This Court has asked for the Solicitor General's views in *Kernats by Kernats* v. *Smiths Industries Medical Systems, Inc.*, 669 N.E.2d 1300 (Ill. App. Ct.), appeal denied, 675 N.E.2d 634 (Ill. 1996), pet. for cert. filed, 65 U.S.L.W. 3632 (No. 96-1405). Although *Smiths Industries* presents the question of how *Medtronic*'s preemption analysis should be applied to investigational and premarket-approved medical devices, it is possible that if review is granted, the Court will clarify its decision in *Medtronic* (including aspects of *Medtronic* on which the lower court relied in this case). Thus, although this case warrants plenary review in its own right, it should at a minimum be held if the *Kernats* petition is granted.

Texaco, Inc., 29 F.3d 1480 (11th Cir. 1994); *Toy Mfrs. of America, Inc.* v. *Blumenthal*, 986 F.2d 615 (2d Cir. 1992); *Allenby*, 958 F.2d 737; *Chemical Specialties Mfrs. Ass'n* v. *Clark, Inc.*, 482 F.2d 325 (5th Cir. 1973); *Chemical Specialties Mfrs. Ass'n* v. *Lowery, Inc.*, 452 F.2d 431 (2d Cir. 1971); *Pinckney* v. *Zep Mfg., Co.*, 1997 WL 204903 (N.D.N.Y. Apr. 15, 1997); *Burch*, 366 A.2d 1079; *Moore* v. *B&C Family Ctr., Inc.*, 272 N.W.2d 150 (Mich. Ct. App. 1978).

The significance of this case, however, extends well beyond the question of the scope of FHSA preemption. When Congress enacted the current version of the FHSA preemption clause in 1976, it did so with the avowed purpose of creating "a uniform Federal preemption clause" for the FHSA, the Flammable Fabrics Act (15 U.S.C. § 1203(a)), the Consumer Product Safety Act (*id.* § 2075(a)), and the Poison Prevention Packaging Act (*id.* § 1476(a)). S. Rep. No. 251, 94th Cong., 2d Sess. 4, *reprinted in* 1976 U.S.C.C.A.N. 993, 996; H.R. Conf. Rep. No. 1022, 94th Cong., 2d Sess. 27-28, *reprinted in* 1977 U.S.C.C.A.N. 1030. In view of Congress's stated objective that these provisions be co-extensive, any interpretation of the FHSA preemption clause is likely to be relevant in cases involving these other statutes as well.

There are many other provisions in the United States Code that specifically preempt nonidentical state "requirements" relating to "labeling." These include not only FIFRA (7 U.S.C. § 136v), which applies to thousands of pesticides and other chemicals and has spawned an enormous body of case law (see pages 11-12, *supra*), but also at least 10 other provisions.[14] Each of these

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[14] See (1) 15 U.S.C. § 1278 note (preempting state "requirement[s] relating to cautionary labeling" for toys, games, balloons, marbles and other products that present choking hazards to children); (2) *id.* § 1461 (preempting state laws governing "labeling" of certain consumer products); (3) *id.* § 2311(c) (preempting certain state "requirement[s]" that relate to warranties in "labeling"); (4) 21 U.S.C. § 343-1(a) (preempting certain state "requirements" relating to food "labeling"); (5) *id.* § 467e (preempting certain state "requirements" relating to poultry "labeling"); (6) *id.* § 678 (preempting certain state "requirements" relating to meat "labeling"); (7) *id.* § 1052 (preempting certain state "requirements" relating to egg product "labeling"); (8) 42 U.S.C. § 6297(a) (preempting

statutes gives rise to the same issue that is presented in this case: whether a federal law that preempts state "labeling" requirements permits a State to impose warning requirements in point-of-sale signs (or through other channels outside the product's "label"). This issue has in fact arisen under several of these other statutes.[15]

The issues raised by this case extend even beyond cases involving the FHSA, FIFRA, the Consumer Product Safety Act, and the other 12 labeling statutes noted above. The Court of Appeal's reasoning illustrates the widespread confusion in the lower courts about post-*Medtronic* express preemption analysis in general. Specifically, the lower court reached suspect conclusions about (1) the meaning of *Medtronic* and the applicability of its "general/specific" distinction to statutes other than the Medical Device Amendments, 21 U.S.C. § 360k(a); (2) the propriety of an approach under which courts "broadly interpret the preemption

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certain state "labeling requirements" relating to energy consumption or water use with respect to certain products); (9) *id.* § 6363(e)(1) (preempting certain state labeling requirements concerning containers of recycled oil); (10) *id.* § 14322(e) (preempting certain state "labeling requirement[s]" for rechargeable batteries and rechargeable consumer products). See also 57 Fed. Reg. 38758, 38759 (Aug. 27, 1992) (Department of Agriculture regulation preempting state "labeling requirements" concerning animal vaccines).

[15] See, *e.g.*, *Moe* v. *MTD Prods., Inc.*, 73 F.3d 179, 182-83 (8th Cir. 1995) (holding state common law failure-to-warn claim based on deficiency in federal labeling preempted under Consumer Product Safety Act, 15 U.S.C. § 2075(a)); *Cortez* v. *MTD Prods., Inc.*, 927 F. Supp. 386, 391 (N.D. Cal. 1996) (same) ("permitting plaintiff to recover on his failure to warn theory would upset the careful balancing of interests that Congress, through the [CPSC], sought to achieve when it prescribed the warning label regulations" for lawn mowers); *Lacey* v. *Lorillard Tobacco Co.*, 956 F. Supp. 956, 962-64 (N.D. Ala. 1997) (holding common-law failure to warn claim preempted by Federal Cigarette Labeling and Advertising Act, 15 U.S.C. §§ 1331-1340). See also *Lynnbrook Farms* v. *Smithkline Beecham Corp.*, 79 F.3d 620, 625, 629-30 (7th Cir.) (state common law claims preempted by Department of Agriculture regulation preempting state "labeling requirements" relating to animal vaccines), cert. denied, 117 S.Ct. 178 (1996).

provision of federal statutes with limited applicability and narrowly interpret those statutes with general applicability" (App., *infra*, 9a); (3) the appropriateness of applying the facial challenge standard to a preemption defense asserted in an enforcement action; and (4) the extent to which preemption cases involving common law claims are inapplicable to statutory preemption cases. Each of these holdings has broad relevance to a wide array of express preemption cases.

The Court of Appeal's far-reaching pronouncements are especially troubling (and deserving of this Court's review) because, under California law, they must be followed by every trial court in the State. See *Auto Equity Sales, Inc.* v. *Superior Court of Santa Clara County*, 369 P.2d 937, 940 (Cal. 1962). Unless corrected by this Court, the Court of Appeal's reasoning and analysis thus may go far in undermining the preemption defense in actions brought in the California courts.

Moreover, this case is important because it involves Proposition 65. Proposition 65 is a highly controversial experiment in citizen-imposed warning requirements at the state level. See Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 ECOLOGY L.Q. 303, 305 (1996) ("The statute has received extraordinary national attention * * * and has been alternatively labeled revolutionary and wildly irresponsible.") (footnotes omitted). Applicable throughout the most populous State in the Union, the statute now covers 433 substances classified by California as carcinogens and another 187 substances classified as reproductive toxins. See Letters Desk, L.A. Times, Sept. 8, 1997, at B4 (letter from Cal. EPA official). Many of these substances (including their labels and labeling) are already regulated by the federal government pursuant to FHSA, FIFRA and other preemptive federal regimes. Environmental activists have pushed for legislation modeled after Proposition 65 in other states. See, e.g., An Act Entitled The "Massachusetts Citizens' Right To Know Act," 1997 MA S.B. 488 (Jan. 1, 1997) (available in LEXIS).

Finally, the logic of the Court of Appeal's decision, if followed by other courts, could eviscerate the FHSA preemption provision and impair the CPSC's regulatory authority. The lower

court's suggestion that "general" requirements are not preemptive (or preempted) would severely impair the FHSA preemption provision, because (as the Illinois Supreme Court has correctly observed), most of the "cautionary labeling requirements" prescribed directly by the FHSA apply generally to a range of substances. See pages 19, 29-30, *infra*; *Busch*, 662 N.E.2d at 406. At the same time, the Court of Appeal's cramped reading of the statutory term "directions for use" will, if followed in other cases, have the undesirable effect of limiting the range of "labeling" over which the CPSC may exercise regulatory authority.

III. THE COURT OF APPEAL'S DECISION IS MANIFESTLY INCORRECT

The decision below is manifestly erroneous. Indeed, several of the errors described above — such as the Court of Appeal's misapplication of the standard for facial challenges to this enforcement action, its derivation from *Medtronic* of the "rule" that broad preemption provisions must be interpreted narrowly and narrow provisions broadly, and its remarkable suggestion that common law preemption cases are irrelevant to cases involving the preemption defense in statutory enforcement actions — are, for reasons already explained, so egregiously mistaken that they may warrant summary reversal. And there are many other important flaws in the Court of Appeal's analysis, of which we will address only a few here.

1. *The Court Of Appeal Failed To Grasp That State-Imposed Warning Requirements Are Necessarily Premised Upon A Perceived Deficiency In The Product's Federally Required "Label" And Thus Are Expressly Preempted By The FHSA*. Contrary to the Court of Appeal's conclusion, the FHSA does not preempt only those warnings and other cautionary statements that state law requires to be *included in* a product's "labeling." Instead, the reference to state "cautionary labeling requirements" should be understood to encompass any requirement to make cautionary statements that is triggered by some perceived deficiency in the product's "label" or "labeling." There is ample support in the legislative history of the FHSA for this common-sense interpretation. See H.R. Rep. No. 325, 94th Cong., 1st Sess. 22 (1975) (stating that "[u]nder existing law, section 18 of the Federal Hazardous Substances Act preempts all differing state laws *pertaining to* precautionary labeling of

hazardous substances") (emphasis added). There also is support for that interpretation in this Court's decision in *Cipollone* and in numerous federal decisions concerning FIFRA's preemption of common law failure-to-warn claims. See pages 11-12, *supra*.[16]

The approach taken by the Court of Appeal would permit the States easily to circumvent the FHSA's preemptive command through requirements to post signs at the point of sale, send letters or make phone calls to customers, or run television commercials or newspaper ads. Under the Court of Appeal's view, the imposition of state cautionary requirements through these means could escape preemption entirely, and States would be free not only to second-guess the federal regulator's judgment concerning what warnings are necessary to protect the public health but also to impose undesirable burdens on interstate commerce. The statements mandated by States through alternative media could even make direct reference to the product's label, or contradict the warnings in that label, without being preempted. That cannot be the law.

2. *Even If The FHSA Only Preempts State Requirements To Provide Warnings In "Cautionary Labeling," That Term Includes Point-Of-Sale Signs*. The FHSA, by its terms, preempts state "cautionary labeling requirements" that are "applicable to" either the product's "packaging" or the hazardous "substance" itself. Plainly, the warnings contained in a point-of-sale sign are "applicable to" the substance discussed by the warnings and constitute "cautionary" messages. Under the Court of Appeal's approach, the only remaining issue is whether the point-of-sale signs in which the warnings must be placed qualify as "labeling" under the FHSA. For at least two reasons, such signs do qualify as "labeling."

a. The FHSA does not define the term "labeling," but it does define the term "label." See note 3, *supra*. The FHSA provision that defines "label" as "a display of written, printed, or graphic

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[16] The Court of Appeal stated that "an enforcement action never requires the court to assess the adequacy of the label." App., *infra*, 21a. But that is simply untrue. Unless the labels affixed to petitioner's products fail to satisfy Proposition 65, there is no valid basis for this enforcement action or for the civil penalties imposed in this case.

matter upon the immediate container of any substance" also makes clear that any warning or disclosure "requirement" under FHSA that must be included in the "label" must also appear "on all *accompanying literature* where there are *directions for use*, written or otherwise." 15 U.S.C. § 1261(n) (emphasis added). Without explanation, the Court of Appeal assumed that "accompanying literature" containing "directions for use" was part of the definition of FHSA "labeling." And since the CPSC's regulations make clear that "accompanying literature" includes point-of-sale signs (see note 3, *supra*), the only remaining question for preemption purposes was whether the Proposition 65 warnings provided "directions for use" within the meaning of the statute.

In answering that question in the negative, the Court of Appeal incorrectly disregarded the CPSC's expert interpretation of the statute. According to the CPSC, although a "warning that a product can cause cancer or birth defects is not an express direction for use," it nevertheless "conveys the information that, in using the product, steps should be taken to minimize or eliminate exposure." Advisory Opinion No. 312, at 3 (Mar. 6, 1991). The Commission explained (*id.* at 3-4):

> Stated another way, the warning itself can also serve as a direction for use. * * * Thus, for example, a product having flammable vapors might have a statement of principal hazard, such as "FLAMMABLE," that could serve also as the required statement of action to be avoided, which, if stated separately, might read "do not use near open flame." Similarly, the statement of principal hazard "HARMFUL IF SWALLOWED" could negate the need to state additionally "for external use only." Also, the statement "VAPOR HARMFUL" could also serve instead of an additional statement to "avoid prolonged inhalation of vapors."

Thus, even warnings that "do[ ] not necessarily convey specific actions to be taken in the use of the product" can "convey information about how the product should be used (steps should be taken to reduce exposure)"; and "[i]t follows" that signs containing such warnings are "labeling under FHSA [section] 2(n)." *Ibid.* The Court of Appeal erred in refusing to give deference to this eminently reasonable agency interpretation.

b. Point-of-sale signs constitute "labeling" for another reason. Although the FHSA does not define that term, it is a well-established concept under federal law. Since 1938, the Food, Drug & Cosmetic Act (FDCA) has defined "labeling" broadly to include "all labels and other written, printed, or other graphic matter (1) upon any article or any of its containers or wrappers, or (2) *accompanying such article*." 21 U.S.C. § 321(m) (emphasis added). See generally *Kordel* v. *United States*, 335 U.S. 345, 347-50 (1948) (discussing breadth of "labeling" under FDCA). That definition of "labeling" should be compared with the much narrower definition of "label" under the FDCA, which is essentially identical to the FHSA's definition of "label."[17] In the absence of a statutory definition of "labeling" in the FHSA, the Court of Appeal should have looked to the settled meaning of that term of art in these other federal-law contexts. The FHSA's definition of the more restrictive term "label" is obviously patterned after the definition of that term in the FDCA and FIFRA, making it particularly sensible to look to those statutes for the meaning of the broader companion term "labeling."

Moreover, the CPSC (and before it the FDA, which administered the FHSA before 1976) have interpreted the FHSA preemption provision broadly to encompass not only state requirements that prescribe the precise content of "labeling" *but also their functional equivalent*. According to a regulation adopted by both agencies and in force for more than a decade:

> Federal preemption applies to any labeling requirement intended *to serve as* or be a part of, *or is in the nature of*, precautionary labeling. Precautionary labeling includes such

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[17] See FDCA, 21 U.S.C. § 321(k) ("The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article * * *."); FHSA, 15 U.S.C. § 1261(n) ("The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any substance * * *."). Compare also 7 U.S.C. § 136(p)(1) (defining "label" under FIFRA as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers") with *id.* § 136(p)(2) (defining "labeling" under FIFRA as including "all labels and all other written, printed, or graphic matter — (A) *accompanying the pesticide or device at any time*") (emphasis added).

> information as warnings, * * * disclosure of hazards, antidote information, * * * and other similar labeling requirements.

21 C.F.R. § 191.4 (1973) (quoted in 37 Fed. Reg. 18628, 18629 (Sept. 13, 1972)) (emphasis added); 16 C.F.R. § 1500.7 (1974) (quoted in 38 Fed. Reg. 27012, 27016 (Sept. 27, 1973)) (emphasis added).[18] Thus, the CPSC was long on record that *all* state requirements targeting the same risk that "serve as" or are "in the nature of" precautionary labeling are preempted, regardless of whether they mandate the inclusion of statements in product "labeling." The Court of Appeal failed to consider this long-standing agency interpretation.

3. *The Court Of Appeal Erroneously Applied To The FHSA The "General/Specific" Distinction Set Forth In* Medtronic. The Court of Appeal evidently failed to grasp that the *holding* of *Medtronic* largely rested on how the unique language of the MDA's preemption provision had been *interpreted by the FDA*. The majority in *Medtronic* stated that its "interpretation of the pre-emption statute is substantially informed" by the "FDA regulations interpreting the scope of § 360k's pre-emptive effect." 116 S. Ct. at 2255; see also *id.* at 2260-61 (Breyer, J.) (same). "[T]he critical importance of device-specificity in [the plurality's] (and the FDA's) construction of § 360k," *id.* at 2259, which formed the basis for the Court's decision, was derived from the FDA's regulation interpreting the statute. There is no similar interpretation of FHSA's preemption clause by the CPSC that endorses the "general/specific" gloss placed on that statute by the Court of Appeal. Indeed, the CPSC's interpretation of the FHSA suggests that the cautionary requirements imposed pursuant to Proposition 65 in this case are preempted.

The "general/specific" distinction is especially inapposite to the FHSA because, as explained above (at pages 19, 24-25), many

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[18] This regulation was revoked in 1982 only because aspects of it — in particular, its statement that "Federal preemption does not apply to a State or local *ban* on a household product" (16 C.F.R. § 1500.7(d) (1974) (emphasis added)) — "became incompatible with" changes made to the FHSA preemption provision in 1976. See 47 Fed. Reg. 57489 (Dec. 27, 1982).

of the warnings and cautionary statements mandated by the statute itself apply to large numbers of hazardous substances. See, *e.g.*, 15 U.S.C. § 1261(p)(1)(C) (requiring the signal word "DANGER" in labeling of all hazardous substances that are "extremely flammable, corrosive, or highly toxic"). Yet there can be no serious doubt that such warnings constitute "cautionary labeling requirements under section [1261(p)]," which trigger preemption under the FHSA's preemption provision. 15 U.S.C. § 1261 note. Moreover, the Court of Appeal's conclusion that "a general warning for a variety of products" does not trigger preemption (App., *infra*, 13a) would deprive even specific warnings relating to a single hazardous substance of preemptive force, because many such substances are a component of multiple "products." And finally, the Court of Appeal's conclusion that the federal requirements in this case are "general" overlooks the toluene-specific warnings mandated in this case by the CPSC. See page 3, *supra*.

4. *The Court Of Appeal's Decision Leads To Absurd Results*. The Court of Appeal's analysis defies common sense. In the Court of Appeal's view, a state requirement to post point-of-sale signs that include warnings concerning a hazardous substance (and targeting the same risk as a federally mandated product warning) is preempted by the FHSA only if the signs contain "directions for use." But there is absolutely no reason — and certainly none suggested by the Court of Appeal — why Congress would have intended to draw such an irrational distinction.

Under the Court of Appeal's analysis, a sign consisting of a single prominent warning ("**GASES HARMFUL**") *would not* be preempted whereas another sign bearing the same warning (in much smaller and less conspicuous typeface) *would* be preempted if it also contained at the bottom in minuscule typescript the statement: "Use product only in temperatures of less than 120 degrees Fahrenheit." Yet the interference with the agency's expert assessment about what warnings are needed is, if anything, greater with respect to the first sign, because the mandated warning is more prominent. When all is said and done, there is no reason why the inclusion of "directions for use" (in the constrictive sense that the Court of Appeals understood that term) should be decisive in determining whether state cautionary requirements are preempted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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APPENDICES

APPENDIX A

The PEOPLE ex rel. Daniel E. LUNGREN, as Attorney General, etc., Plaintiff and Respondent,
v.
COTTER & COMPANY, Defendant and Appellant;
As You Sow, Intervener and Respondent.

No. A070904.

Court of Appeal, First District, Division 2, California.

March 31, 1997.

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Thomas J. Graves, Charlottesville, VA, McDermott, Will & Emery, Nathalie F.P. Gilfoyle, Washington, DC, Thomas A. Ryan, Los Angeles, Amici Curiae on behalf of Defendant and Appellant.

Daniel E. Lungren, Attorney General of the State of California, Roderick E. Walston, Chief Assistant Attorney General, Theodora Berger, Assistant Attorney General, Craig Thompson, Supervising Deputy Attorney General, Edward G. Weil, Susan S. Fiering, Deputy Attorneys General, for Plaintiff and Respondent.

Clifford A. Chanler, Mark Todres, Jenny Cohn, Chanler & Somers, Intervener and Respondent.

LAMBDEN, Associate Justice.

Cotter & Company (Cotter) appeals the trial court's denial of its summary judgment motion and the granting of the People's cross motion for summary adjudication as to Cotter's affirmative defense alleging preemption. Cotter contends the Federal Hazardous Substances Act (FHSA) preempts California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). We find the FHSA does not preempt the warning requirements of Proposition 65 and affirm.

BACKGROUND

As You Sow (AYS), a nonprofit organization, investigates and sometimes litigates possible Proposition 65[1] violations. Health and Safety Code[2] section 25249.6 requires warnings for products causing cancer or reproductive toxicity. Toluene is a reproductive toxin which requires a warning pursuant to Proposition 65.[3]

On December 10, 1992, AYS sent a 60 day notice pursuant to section 25249.7 to the Attorney General of the State of California alleging that Cotter and three other paint and coatings manufacturers failed to provide warnings of toluene exposure in violation of Proposition 65.[4] Cotter is a national member owned cooperative with 300 to 500 True Value Hardware stores in California.

On September 17, 1993, the Attorney General filed a suit against Cotter and three other companies[5] alleging they violated Proposition

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[1] Health and Safety Code section 25249.5 et seq., which became effective January 1, 1987, codifies Proposition 65.

[2] Unless otherwise designated, all code sections refer to the Health and Safety Code.

[3] Toluene became listed as a reproductive toxin on January 1, 1991 (Cal. Code Regs., tit. 22, § 12000), and warnings became required pursuant to section 25249.10, subdivision (b), as of January 1, 1992.

[4] Proposition 65 provides for citizen enforcement of the statute. Section 25249.7, subdivision (d), states: "Actions pursuant to this section may be brought by any person in the public interest if (1) the action is commenced more than sixty days after the person has given notice of the violation which is the subject of the action to the Attorney General and the district attorney and any city attorney in whose jurisdiction the violation is alleged to occur and to the alleged violator, and (2) neither the Attorney General nor any district attorney nor any city attorney or prosecutor has commenced and is diligently prosecuting an action against such violation."

[5] The three other companies settled with the People and agreed to the entry of consent judgments which ordered them to comply with Proposition 65 and pay penalties and restitution.

65 and the Business and Professions Code section 17200 et seq. On July 23, 1994, Cotter and the People entered into a Permanent Injunction Pursuant to Stipulation requiring Cotter to take certain steps to provide warnings for its paint products.

Cotter filed a motion for summary judgment alleging Proposition 65's regulations involved "cautionary labeling requirements" as defined by the FHSA. Consequently, Cotter argued, federal law has preempted Proposition 65. In addition, Cotter alleged it could only comply with Proposition 65 by labeling its products; therefore Proposition 65 constituted a de facto labeling requirement. The People responded by filing opposition to Cotter's motion and a cross motion for summary adjudication to Cotter's fifth affirmative defense, which alleged preemption of Proposition 65 by the FHSA. On March 9, 1993, the court denied summary judgment to Cotter and granted summary adjudication to the People on the fifth affirmative defense.

Cotter and the People entered into a consent judgment on June 9, 1995, resolving the litigation and requiring Cotter to pay $275,000 as penalties and restitution for the Proposition 65 violations. The consent judgment permitted Cotter to appeal from the order on preemption.

Statutory Background

Proposition 65

Proposition 65 states, in part: "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual...." (§ 25249.6.) Twelve months after the statute designates a substance as toxic, products containing the listed toxic substance must have warnings about the health risks. (§ 25249.10, subd. (b).)

The statute does not define "warning," but explains: "'Warning' within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the

warning accomplished is clear and reasonable." (§ 25249.11, subd. (f).) The regulations describe four types of "safe harbor" warnings for consumer products: product labeling, "shelf labeling, signs, menus, or a combination thereof." (Cal. Code Regs., tit. 22, § 12601, subd. (b)(1)(B).)

The warnings must be "prominently placed upon a product's label or other labeling or displayed at the retail outlet with such conspicuousness, as compared with other words, statements, designs, or devices in the label, labeling or display as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use." (Cal. Code Regs., tit. 22, § 12601, subd. (b)(3).) Thus, a merchant can comply with Proposition 65 by posting a sign stating the products are known to the state to cause cancer and/or are reproductively toxic.

The FHSA

Congress enacted the FHSA in 1960 and the Act itself does not contain a section stating its purpose. (See *Lee* v. *Boyle-Midway Household Products, Inc.* (W.D. Pa.1992) 792 F. Supp. 1001, 1008.) However, the House Committee on Interstate and Foreign Commerce stated, "The purpose of this bill is to provide nationally uniform requirements for adequate cautionary labeling of packages of hazardous substances which are sold in interstate commerce and are intended or suitable for household use." (*Id.*, *quoting* H.R. Rep. No. 1861, 86th Cong., 2d Sess. 1 (1960), reprinted in 1960 U.S. Code Cong. & Admin. News, No. 2, p. 2833.)

In 1966, Congress added a limited preemption provision to protect manufacturers from having to create different labels to comply with varying state regulations. It modified the preemption provision in 1976 to state: "'Except as provided in paragraphs (2) and (3), if a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) [subsec. (p) of this section or section 1262(b) of this title] designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under section

2(p) or 3(b) [subsec. (p) of this section or section 1262(b) of this title].'" (15 U.S.C. § 1261 note (b)(1)(A) (hereinafter 15 U.S.C. § 1261 note).)

Although the FHSA does not define "cautionary label," it does define label as the following: "The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the case of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (1) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (2) on all accompanying literature where there are directions for use, written or otherwise." (15 U.S.C. § 1261(n).)

DISCUSSION

Cotter raises two issues on appeal: (1) Does the FHSA preempt Proposition 65 warnings because point of sale signs are labels as defined by the FHSA? (2) If point of sale signs are not labels, does the FHSA still preempt Proposition 65 because the state statute imposes a de facto labeling requirement? We address each of these issues separately.

I. Point of Sale Signs Are Not Labels Under the FHSA

Cotter contends the court erred in denying its summary judgment motion because Proposition 65 imposes a "cautionary labeling requirement" which is preempted by the FHSA. Since Cotter presents a facial challenge to Proposition 65, it must establish Proposition 65 would not be valid under any set of circumstances. (*Chemical Specialties Mfrs. Ass'n, Inc.* v. *Allenby* (9th Cir.1992) 958 F.2d 941, 943, *cert. den.* (1992) 506 U.S. 825, 113 S.Ct. 80, 121 L.Ed.2d 44 (*Allenby*).) Thus, to find preemption, we "'must determine that all possible consumer product warnings that would satisfy Proposition 65 conflict with provisions'" of the FHSA.

(*Comm. of Dental Amalgam Mfrs. & Distribs.* v. *Stratton* (9th Cir.1996) 92 F.3d 807, 810 (*Stratton*).)

The People claim Cotter could satisfy Proposition 65 by using point of sale signs. This method, they assert, does not conflict with the preemption provision of the FHSA. They rely on *Allenby*, *supra*, 958 F.2d 941, which held such signs are not labels under the FHSA. Cotter, however, claims the Ninth Circuit in *Allenby* misapplied and misinterpreted federal and state law and the trial court erred by following *Allenby*.

In deciding whether *Allenby* represents good law, we first review the federal preemption doctrine and examine the most recent United States Supreme Court decisions. We then explain why *Allenby* correctly found point of sale signs are not labels under the FHSA.

A. Standard of Review

The trial court denied Cotter's motion for summary judgment based on preemption and granted the People's motion for summary adjudication to Cotter's defense of preemption. Summary adjudication was proper only if the defense of preemption presented no triable issue of material fact and Cotter could not raise the defense as a matter of law. (Code Civ. Proc., § 437c, subd. (f)(1).) Since the parties do not dispute the facts related to preemption and the summary adjudication raises a purely legal question, we employ de novo review. (*Schrader* v. *Scott* (1992) 8 Cal. App.4th 1679, 1684, 11 Cal.Rptr.2d 433.)

B. Preemption Doctrine

"Preemption analysis starts with the presumption that the traditional police powers of states are not displaced by federal law unless displacement was the 'clear and manifest purpose of Congress.'" (*Allenby*, *supra*, 958 F.2d 941, 943. *Accord* with *Medtronic, Inc.* v. *Lohr* (1996) — U.S. —, —, 116 S.Ct. 2240, 2248, 135 L.Ed.2d 700 (*Medtronic*).)[6] One reason for this

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[6] Justice Stevens delivered the opinion of the court. Justices Kennedy, Souter, Ginsburg, and Breyer joined with respect to pages 2245-2251 (Parts I, II, and III); pages 2253-2258 (Part V); and page 2259 (Part VII). Justices Kennedy, Souter, and Ginsburg joined with respect to pages

presumption is Congress has the power to make its intention clear. "[I]f the court erroneously finds preemption, the State can do nothing about it, while if the court errs in the other direction, Congress can correct the problem." (*Ibid.*)

The second presumption underlying a preemption analysis requires a determination of Congress's purpose, which "'is the ultimate touchstone' in every pre-emption case. [Citations.]" (*Medtronic*, supra, — U.S. ——, ——, 116 S.Ct. 2240, 2250.) We determine intent primarily "from the language of the pre-emption statute and the 'statutory framework' surrounding it. [Citation.]" (*Id.* at p. ——, 116 S.Ct. at p. 2251.) "Also relevant, however, is the 'structure and purpose of the statute as a whole,' [citation], as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." (*Ibid.*)

If the statute does not have an express preemption clause, state law is only preempted if (1) the law actually conflicts with federal law, or (2) federal law so thoroughly occupies a legislative field "'as to make reasonable the inference that Congress left no room for the States to supplement it.' [Citation.]" (*Cipollone* v. *Liggett Group, Inc.* (1992) 505 U.S. 504, 516, 112 S.Ct. 2608, 2617, 120 L.Ed.2d 407 (*Cipollone*).) "When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a 'reliable indicium of congressional intent with respect to state authority' [citation], 'there is no need to infer congressional intent to pre-empt state laws from the substantive provisions' of the legislation. [Citation.]" (*Id.* at p. 517, 112 S.Ct. at p. 2618.)

In this case, Congress enacted an express preemption clause and we only need to "identify the domain expressly pre-empted." (*See Cipollone*, *supra*, 505 U.S. 504, 517, 112 S.Ct. 2608, 2618.)

2251-2253 (Part IV) and pages 2258-2259 (Part VI). Justice Breyer filed an opinion concurring in part and concurring in the judgment. Justice O'Connor filed an opinion concurring in part and dissenting in part, in which Justices Rehnquist, Scalia, and Thomas joined. All references, unless otherwise specified, refer to Justice Stevens's opinion.

Moreover, we must narrowly read the preemption clause because Proposition 65 is an instance of the state exercising its police power. (*Medtronic*, *supra*, — U.S. —, —, 116 S.Ct. 2240, 2250; *Ketchum* v. *Hyundai Motor Co.* (1996) 49 Cal. App. 4th 1672, 1678, 57 Cal. Rptr. 2d 595.)

C. Cipollone and Medtronic

The two most recent United States Supreme Court cases to consider preemption are *Cipollone*, *supra*, 505 U.S. 504, 112 S.Ct. 2608 and *Medtronic*, *supra*, — U.S. —, 116 S.Ct. 2240. Both the People and Cotter contend *Cipollone* supports their position. The Supreme Court decided *Medtronic* while this appeal was pending, and both parties discussed its impact on this appeal at oral argument.

In *Cipollone*, *supra*, the United States Supreme Court found the amended Public Health Cigarette Smoking Act of 1969 (Smoking Act) preempted common law claims based on a failure to warn about the hazards of smoking, but not those premised on express warranty, intentional fraud and misrepresentation, or conspiracy. (505 U.S. 504, 112 S.Ct. 2608, 120 L.Ed.2d 407.) The federal statute set forth the exact warning to be placed on each package[7] and the preemption clause specified "'[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.'" (*Id.* at p. 515, 112 S.Ct. at p. 2617.)

When determining whether federal law expressly preempted the common law claims, the court in *Cipollone*, *supra*, held the following as the central inquiry: "[W]e ask whether the legal duty that is the predicate of the common-law damages action constitutes a 'requirement or prohibition based on smoking and health ... imposed under State law with respect to ... advertising or promotion,' giving that clause a fair but narrow reading." (505

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[7] The Smoking Act required the following warning: "'WARNING: THE SURGEON GENERAL HAS DETERMINED THAT CIGARETTE SMOKING IS DANGEROUS TO YOUR HEALTH.'" (*Cipollone*, *supra*, 505 U.S. at p. 508, 112 S.Ct. at p. 2613.)

U.S. 504, 524, 112 S.Ct. 2608, 2621, 120 L.Ed.2d 407.) Thus, federal law preempted state claims based on inadequate warnings about health risks.

The United States Supreme Court further refined preemption analysis in *Medtronic*, *supra*, — U.S. —, 116 S.Ct. 2240. In Medtronic, the manufacturer of a pacemaker argued the Medical Device Amendments of 1976 (MDA) to the federal Food, Drug and Cosmetics Act governed the requirements for medical devices and its preemption clause prevented the plaintiff's claims of negligence and strict liability based on a defective device and inadequate warnings. (*Id.* at p. —, 116 S.Ct. at p. 2250.) The preemption provision under the MDA provided: "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement — [¶] (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and [¶] (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." (21 U.S.C. § 360k(a).)

The court in *Medtronic* stated courts should broadly interpret the preemption provision of federal statutes with limited applicability and narrowly interpret those statutes with general applicability. Accordingly, the court in *Cipollone* broadly interpreted the word "requirement" in the preemption provision because: "The pre-emptive statute in *Cipollone* was targeted at a limited set of state requirements — those 'based on smoking and health' — and then only at a limited subset of the possible applications of those requirements — those involving the 'advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of' the federal statute. [Citation.]" (*Medtronic*, *supra*, — U.S. —, —, 116 S.Ct. 2240, 2252 fn. omitted.)

In contrast to the Smoking Act, the MDA in *Medtronic* applied to all medical devices, warranting a narrow interpretation of "requirement." The court defined "requirement" under the MDA to include only those situations in which the state and federal government had imposed a conflicting "duty" on the manufacturer. (*Medtronic*, *supra*, — U.S. —, —, 116 S.Ct. 2240, 2251.) The FDA approved the marketing of the pacemaker in *Medtronic*

because it was "'substantially equivalent' to devices already on the market," and had not specifically evaluated the pacemaker. (*Id.* at p. ----, 116 S.Ct. at p. 2248.) Accordingly, the court found the MDA had not issued "any requirement" applicable to this device and it did not preempt the state claim alleging negligent design. (*Id.* at p. ----, 116 S.Ct. at p. 2249.)

The court in *Medtronic* also held the MDA did not preempt claims based on inadequate labeling. The MDA required manufacturers of every medical device to include a label containing "'information for use, ... and any relevant hazards, contraindications, side effects, and precautions.' [Citation.]" (*Medtronic*, *supra*, --- U.S. ----, ----, 116 S.Ct. 2240, 2256.) The labeling requirements did not apply specifically to the pacemaker; therefore, the court found the federal government had not imposed a labeling "requirement" for the pacemaker.

The court explained why a decision regarding preemption should consider the "generality" of the federal statute: "The generality of those requirements make [sic] this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." (*Medtronic*, *supra*, --- U.S. ----, ----, 116 S.Ct. 2240, 2258.) Instead, "the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." (*Ibid.*)

When both the state and federal requirements reflect "generic concerns" rather than specific regulations, they probably will not conflict, resulting in no preemption. (*Medtronic*, *supra*, --- U.S. ----, ----, 116 S.Ct. 2240, 2258.) Preemption occurs "only where a particular state requirement threatens to interfere with a specific federal interest." (*Id.* at p. ----, 116 S.Ct. at p. 2257.)

D. The FHSA, Proposition 65, and Preemption

Only one case, *Allenby*, *supra*, has reviewed preemption under the FHSA and Proposition 65. (958 F.2d 941.) It held the FHSA did not preempt Proposition 65.[8]

Cotter argues *Allenby* does not represent good law because it conflicts with the holding in *Cipollone*, contradicts other state and federal decisions made post-*Cipollone*, and ignored and failed to defer to the conclusions of the Consumer Product Safety Commission (CPSC). To support its contention, Cotter cites one other Proposition 65 case in the district court (*Committee of Dental Amalgam Alloy Mfrs.* v. *Henry* (S.D. Cal.1994) 871 F. Supp. 1278), which was recently reversed in *Stratton*, *supra*, 92 F.3d 807, and tort claims preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Prior to assessing each of Cotter's criticisms of *Allenby*, we briefly summarize *Allenby's* analysis of preemption under the FHSA and conduct our own independent analysis of preemption and the FHSA.

1. Allenby

When analyzing preemption under the FHSA, the court in *Allenby*, *supra*, 958 F.2d 941, 946 noted the preemption provision in the FHSA only applies to "cautionary labels" on packages (15 U.S.C. § 1261 note). The Act defines labels as including accompanying literature only if the material contains "directions for use." (15 U.S.C. § 1261(n).) Thus, if point of sale signs were not "directions for use," they represented a method in which a manufacturer could satisfy Proposition 65 without requiring warning labels in addition to the FHSA.

The court rejected the argument that Proposition 65 warnings "impliedly" direct the consumer to handle the product to "avoid or minimize direct exposure" and were therefore directions for use. (*Allenby*, *supra*, 958 F.2d 941, 949.) The court explained this was a "nonsensical reading" of the term "directions for use" and it

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[8] *Allenby* also found Proposition 65 was not preempted by the Federal Insecticide, Fungicide and Rodenticide Act.

agreed with the lower court's comments during oral argument about a sign stating, "'this product may cause birth defects.'" The Ninth Circuit quoted the lower court as responding: "'[D]oesn't tell you whether it's going to cause defects if you pour it on your feet, or if you drink it, or if you poke it in your ear, it just says that it may cause birth defects. How is that a direction for use?'" (*Ibid.*) Instead, the court in *Allenby* determined Congress's intent more likely related to "how much of a detergent to use, or how long a paint solvent should be mixed."[9] (*Ibid.*)

The court in *Allenby* concluded Proposition 65 did not frustrate any congressional purpose. The FHSA regulates cautionary labeling to promote uniformity but permits the states through the use of point of sale signs to regulate the sale and use of hazardous chemicals. (*Allenby*, *supra*, 958 F.2d 941, 950.)

2. Allenby's analysis of labels under the FHSA remains good law post-Cipollone

(i) Predicate duty analysis does not apply to general statutes

Cotter argues *Allenby* is not good law because (*Cipollone*, *supra*, 505 U.S. 504, 524, 112 S.Ct. 2608, 2621) held the central inquiry for preemption is whether the state and federal statutes have the same predicate duty. Cotter contends Proposition 65 and the FHSA have the same "predicate duty": the legal duty to warn of toxic dangers.

Cotter, however, does not consider the recent decision of *Medtronic*, *supra*, which explained the predicate duty analysis does

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[9] *Allenby*, *supra*, also found no preemption because the warnings required under Proposition 65 were not "necessarily nonidentical" to the requirements under the FHSA. (958 F.2d at p. 950.) Since neither statute required specific language, a manufacturer could choose to use a label which satisfied both Proposition 65 and the FHSA. However, after *Cipollone*, once Congress has enacted a preemption amendment, the issue is not whether the warnings can never be the same, but whether the warnings are identical. The requirements under Proposition 65 are clearly not identical to the warnings under the FHSA. Thus, we disagree with the holding in *Allenby* to the extent it found no preemption on this basis.

not apply when the federal statute merely requires a general duty to inform users and purchasers of potentially dangerous items. (--- U.S. ---, ---, 116 S.Ct. 2240, 2258, 135 L.Ed.2d 700.) When the predicate for the plaintiff's claims is the general duty to inform users and purchasers of potentially dangerous items and the federal government has not implemented or enforced specific federal requirements, general obligations imposed by the state do not threaten the federal requirements. (*Ibid.*)

Indeed a recent Ninth Circuit opinion, relying on the analysis of *Medtronic*, held the MDA does not preempt Proposition 65 warnings[10] for dental amalgam.[11] (*Stratton*, *supra*, 92 F.3d 807, 810.) "Proposition 65 is a state law of general applicability which was not enacted 'with respect to' medical devices." (*Id.* at p. 813.) Rather, "Proposition 65 applies to all products and services that pose a health risk to the public." (*Ibid.*) The court concluded: "Thus, we hold that the consumer warning requirement under California's Proposition 65 is not 'specific' enough to trigger preemption because it is 'not the kind[ ] of requirement[ ] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements.'" (*Ibid.*)

Following both *Medtronic* and *Stratton*, the "predicate duty" analysis for preemption does not apply when both the federal and state statutes require a general warning for a variety of products and do not target specific products. As noted above, Proposition 65 is a general statute which applies to all products and services posing a health risk. Similarly, the FHSA is a general statute which requires warnings on labels for substances it determines are hazardous. (15 U.S.C. § 1261.) A "'hazardous substance'" includes: "Any substance or mixture of substances which (i) is

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[10] Proposition 65 imposes consumer warning requirements for dental amalgam because it contained dental mercury.

[11] The two component parts of dental amalgam — dental mercury and amalgam alloy — are separately regulated by the MDA; therefore, the court concluded the MDA covered dental amalgam. (*Stratton*, *supra*, 92 F.3d 807, 810.)

toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." (15 U.S.C. § 1261(f)(1)(A).)

Given the generality of Proposition 65 and the FHSA, Cotter's criticism of *Allenby* for failing to consider the statutes' predicate duty has no merit. Unlike the Smoking Act in *Cipollone*, which provided requirements for a particular product and specified the exact wording for the warning, the requirements of the FHSA apply to a variety of products in numerous industries. In this situation an analysis of the predicate duty becomes meaningless.

(ii) Allenby correctly found point of sale signs are not labels

Allenby's analysis of labels under the FHSA does not contradict the reasoning in either *Cipollone* or *Medtronic*.[12] Our independent examination of Proposition 65 and the FHSA confirms *Allenby's* finding on point of sale signs and the FHSA.

As with any state law regulating health and safety, we begin by presuming Proposition 65 is not displaced. (*Medtronic*, *supra*, — U.S. —, —, 116 S.Ct. 2240, 2248.) Since the FHSA does have a specific preemption clause, we need to determine "the domain expressly pre-empted." (*Cipollone*, *supra*, 505 U.S. 504, 517, 112 S.Ct. 2608, 2618.) We determine this "domain" by examining the language of the preemption statute, its "'statutory framework,'" and the "structure and purpose of the statute as a whole" (*Medtronic*, *supra*, — U.S. at p. —, 116 S.Ct. at p. 2251).

As already stressed, Congress enacted an explicit preemption provision in the FHSA prohibiting a state to establish a cautionary labeling requirement for hazardous substances covered by the FHSA "unless such cautionary labeling requirement is identical to the labeling requirement" in this Act. (15 U.S.C. § 1261 note.)

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[12] We express no opinion about *Allenby's* finding that FIFRA did not preempt Proposition 65 warnings.

The Act defines label as a "display of written, printed, or graphic matter upon the immediate container of any substance ... and (2) on all accompanying literature where there are directions for use, written or otherwise." (15 U.S.C. § 1261(n).)

Congress chose to restrict the definition of a label to include accompanying literature only when that material contains "directions for use." (15 U.S.C. § 1261(n).) These words indicate the warning must tell the user how to use the product. This situation resembles the one in *Medtronic, supra*, where the court refused to interpret "requirement" in the preemption provision of the MDA to mean "remedy" because "if Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it." (*Medtronic, supra*, — U.S. —, — - —, 116 S.Ct. 2240, 2251- 2252.) Similarly, if Congress wanted preemption under the FHSA to apply to all accompanying literature with "implied" directions for use, as Cotter argues, Congress could have specified that.

In addition to examining the language of the FHSA, we must consider Congress's stated purpose. The FHSA itself does not contain a section setting forth its purpose but Congress enacted the FHSA in 1960 to "'provide nationally uniform requirements for adequate cautionary labeling of packages of hazardous substances which are sold in interstate commerce and are intended or suitable for household use.'" (*Moss* v. *Parks Corp.* (4th Cir.1993) 985 F.2d 736, 739, *citing* House Com. on Interstate and Foreign Commerce, Federal Hazardous Substances Labeling Act, H.R. Rep. No. 1861, 86th Cong., 2d Sess. 2 (1960), *reprinted in* 1960 U.S. Code Cong. & Admin. News, No. 2, p. 2833.) When Congress amended the FHSA in 1966, the legislative history discussed the impracticality of having the states produce potentially 50 different labels for a particular hazardous substance. (*Jenkins* v. *James B. Day & Co.* (1994) 69 Ohio St.3d 541, 545, 634 N.E. 2d 998, 1001-1002.)

To assess Congress's purpose we must also consider the structure and framework of the FHSA. Following *Medtronic, supra*, — U.S. —, —, 116 S.Ct. 2240, 2250, we must interpret the words in the preemption statute narrowly when the federal statute and state statute have general applicability.

As already stressed, the FHSA is an extremely broad statute. It applies to numerous products in a variety of industries and it does not require specific language on the labels but "merely requires (1) that labels contain the signal word 'WARNING' or 'CAUTION' and (2) words which describe the potential hazard." (*Allenby*, *supra*, 958 F.2d 941, 950.) Furthermore, the generality of these requirements makes it clear the federal government has not "weighed the competing interests relevant" to the particular hazardous material and has not "reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers" (*Medtronic*, *supra*, --- U.S. ----, ----, 116 S.Ct. 2240, 2258).

Given the FHSA's general applicability, point of sale signs are unlikely to interfere with the federal government's objectives. Point of sale signs obviously do not require manufacturers to develop more than one label for all 50 states. Moreover, point of sale signs allow the state to regulate sales, a distinctively state interest, without imposing additional labeling requirements on packages. Rather than conflicting with the federal government's objectives, they serve to further the purpose of the FHSA by providing a larger audience with information.

Interpreting Proposition 65's warnings as "implied" direction for use to the consumer to take "steps" to "reduce exposure," as Cotter argues, would create an extensive preemption provision under the FHSA. With such a definition, purely informational signs could be considered implied directions for use. For example, signs merely rating material on the product's appropriateness for minors or adults would constitute labeling. Indeed, price tags could be found to be implied directions for use as one should use expensive items sparingly.

We, therefore, conclude *Allenby* correctly found the FHSA does not preempt Proposition 65 point of sale signs.[13]

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[13] The People also argue the FHSA does not preempt Proposition 65 because the state and federal statute warn against different risks. The People contend Proposition 65 addresses harm to the developing fetus (Cal. Code Regs., tit. 22, § 12601, subd. (b)), while the FHSA relates to

3. Distinguishing FIFRA cases

To support its argument of preemption, Cotter cites numerous FIFRA cases which found FIFRA preempted common law claims based on inadequate point of sale warnings.[14] (*Taylor AG Industries* v. *Pure-Gro* (9th Cir.1995) 54 F.3d 555, 560 (*Taylor AG*); *Louisiana-Pacific Corp.* v. *Koppers Co.* (1995) 32 Cal. App. 4th 599, 38 Cal. Rptr. 2d 257; *Papas* v. *Upjohn Co.* (11th Cir. 1993) 985 F.2d 516.) Although the preemption provision in FIFRA is essentially identical to the one in the FHSA,[15] that similarity should not obfuscate the differences between the statutes.

Three material differences distinguish FIFRA cases from this case: (1) FIFRA defines a label more expansively than the FHSA; (2) FIFRA is not simply a labeling statute while the FHSA is; and (3) FIFRA cases are predominantly tort common law cases and this is a Proposition 65 enforcement action.

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the risks of chemical pneumonitis, pneumonia, and pulmonary edema caused by aspiration into the lungs and systemic injury from inhaling the vapor. This argument has no merit because, as Cotter asserts, the FHSA includes reproductive toxicity within the meaning of "toxic" (16 C.F.R., § 1500.3(c)(2)(ii)(C) (1996)).

[14] Cotter points out *Burke* v. *Dow Chemical Co.* (E.D.N.Y. 1992) 797 F. SUPP. 1128, 1140 (Burke) represents the sole post-*Cipollone* case holding FIFRA does not preempt warnings outside of product labeling. The People contend Burke correctly applied the "channels of communication" language contained in *Cipollone*. The court in *Cipollone* stated that even if one channel of communication was preempted, other "channels of communication" were not. (*Cipollone*, *supra*, 505 U.S. 504, 528, 112 S.Ct. 2608, 2623.) The court, however, was referring to obligations outside of advertising or the promotion of cigarettes and the statement does not clarify whether labeling includes point of sale signs. Since we find the preemption question under FIFRA and the FHSA to be different, we do not address Burke's interpretation of the court's use of "channels of communication."

[15] FIFRA's preemption clause provides as follows: "Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." (7 U.S.C. § 136v(b).)

(i) Differences between the statutes

FIFRA broadly defines label as the following: "The term 'labeling' means all labels and all other written, printed, or graphic matter — [¶] (A) accompanying the pesticide or device at any time; or [¶] (B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications...." (7 U.S.C. § 136(p)(2).) Congress designated matter "accompanying" the product as a label without any further qualification. Consequently, FIFRA cases do not help us determine Congress's intent when it limited a label under the FHSA to mean accompanying literature providing "directions for use."

More significantly, when examining the "statutory framework" of FIFRA, the differences between the two federal statutes are magnified. Rather than creating a mere labeling statute, Congress in 1972, "transformed it [FIFRA] into a comprehensive regulatory statute governing the use and sale of pesticides." (*Louisiana-Pacific Corp.* v. *Koppers Co.*, *supra*, 32 Cal. App. 4th 599, 603, 38 Cal. Rptr. 2d 257.) One of the cases emphasized by Cotter, *Taylor AG*, *supra*, 54 F.3d 555, 560, noted the "rigorous label-approval process under FIFRA." The court explained: "Although FIFRA does not prescribe the exact contents of labels, manufacturers are not free, ... to create pesticide labels in any manner they choose. Rather, ... the EPA approves each label only after a careful review of the product data and the draft label." (*Ibid.*)

Given the statutory framework of FIFRA, a broad interpretation of the word "label" under FIFRA is consistent with *Medtronic*. Not only does FIFRA define "label" expansively, but it represents a situation "in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers" (*Medtronic*, *supra*, — U.S. —, —, 116 S.Ct. 2240, 2258).

In contrast, as already stressed, the FHSA does not (1) have a label approval process, (2) specify the wording to be used on the label, or (3) regulate the sale or use of the hazardous products

covered by the federal statute. Instead, as the People contend, Congress has left the states free to regulate the sale and use of these hazardous products. The FHSA has remained a labeling statute and the scope of its preemption differs significantly from FIFRA.[16] Accordingly, cases interpreting FIFRA have "limited relevance" to determinations of preemption and the FHSA. (*See Jenkins* v. *James B. Day & Co.*, *supra*, 634 N.E. 2d 998, 1004, fn. 4.)[17]

(ii) Differences between tort actions and state enforcement actions

An additional reason for contending the FIFRA cases cited by Cotter are irrelevant, according to the People, is because they involve tort claims rather than the state's enforcement of a statute. In response, Cotter claims FIFRA tort cases provide an appropriate method of analysis for federal preemption under the FHSA since the basis for requiring a warning under common law and Proposition 65 is the same. Cotter argues "[w]here the reason is the same, the rule should be the same" (Civ. Code, § 3511), and "[t]he law respects form less than substance" (Civ. Code, § 3528).

As Cotter asserts, enforcement and common law actions pose the same questions and issues in a determination of the "domain expressly preempted." Accordingly, we used *Cipollone* and *Medtronic*, actions in tort, to determine the scope of preemption under the FHSA.

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[16] To the extent *Allenby*, *supra*, 958 F.2d 941, 945 held the issue of preemption arising under FIFRA is identical to that under the FHSA, we disagree. We do agree with *Allenby's* conclusion that the preemption provisions in both statutes are essentially identical.

[17] "Because the FHSA requires no federal agency approval of the precise language which appears on the label of a substance covered by the FHSA, it appears that an inadequate warning claim is more readily preempted for a product covered by FIFRA than would a similar inadequate warning claim be for a product covered by the FHSA. Of course, since this case does not involve FIFRA, we do not resolve this question. We discuss FIFRA merely to explain why cases interpreting that statute may be of limited relevance to the issue in this case." (*Jenkins* v. *James B. Day & Co.*, *supra*, 634 N.E. 2d 998, 1004, fn. 4.)

After determining the preempted domain, the analyses of tort and enforcement actions diverge in a materially significant respect. Once the court determines a common law claim falls within the reach of the preemption clause, the analysis ceases. The federal government's interest in promoting interstate commerce always trumps the individual's interests in receiving damages.

Unlike a tort action, an enforcement action requires the court to establish whether any method of compliance with the state statute falls outside the scope of the preemption provision. (See *Stratton*, *supra*, 92 F.3d 807, 810.) If any method is beyond the reach of the preemption provision, the statute remains valid. The federal statute sets the standards for sufficient warnings (barring any tort claims on this basis), but does not necessarily prohibit the state from requiring warnings consistent with the preemption provision that regulate the use and sale of these products.

Both *Allenby*, *supra*, 958 F.2d 941, 948 and *Taylor AG*, *supra*, 54 F.3d 555, 560 acknowledged this distinction when discussing preemption and FIFRA. The Ninth Circuit in *Taylor AG*, *supra*, rejected the argument "that liability should be imposed upon the Manufacturers for failure to warn arising from alleged deficiencies in advertisements, point-of-sale warnings, and other materials distributed in connections with a sale." (54 F.3d at p. 561, fn. omitted.) The court in *Taylor AG* reconciled its holding with the one in *Allenby* by explaining the court in *Allenby* "merely" held "non-label warnings were not preempted by FIFRA," but *Allenby* admitted "'[t]he argument against product liability suits for inadequate labeling is strong.'" (*Taylor AG*, *supra*, at p. 561, fn. 2, quoting *Allenby*, *supra*, at p. 948.)

Cotter claims the two Ninth Circuit cases, *Allenby* and *Taylor AG*, are inconsistent, with the latter representing the better law. However, as both the People and the court in *Taylor AG* point out, the two courts were simply addressing different types of actions.[18]

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[18] Dicta in *Taylor AG* suggested the court agreed point of sale signs, even under the broad definition of label in FIFRA, did not constitute labeling. The court stated Allenby did not address "whether common law damages could be imposed for the absence of these non-label [point of sale signs] warnings." (*Taylor AG*, *supra*, 54 F.3d 555, 561, fn. 2, italics

In finding Proposition 65 is not preempted under the FHSA, because point of sale signs are not labels and do not provide "directions for use," we are not opening the door to common law tort claims premised on the inadequacy of the product label.

Finally, Cotter claims tort actions and enforcement actions are the same because a company must pay a penalty when it violates the statute. The penalty, Cotter claims, has the same consequences as an award for damages. This argument, however, ignores the vital distinction between the two. As the People point out, an enforcement action never requires the court to assess the adequacy of the label, while that is the task facing the court in a tort action. In an enforcement action, the court simply looks to see whether the company has complied with the mandate of the statute.

4. The CPSC's interpretation of "label" under the FHSA is clearly erroneous

Cotter contends the court in *Allenby* erred by ignoring the CPSC's conclusion that point of sale signs qualify as a "direction for use." In response to a request from the Chemical Specialties Manufacturers Association for an advisory opinion, Clement D. Earhardt, III, from the Office of General Counsel of the CPSC concluded on March 6, 1991, the following: "A warning that a product can cause cancer or birth defects is not an express direction for use. Nevertheless, it conveys the information that, in using the product, steps should be taken to minimize or eliminate exposure. Stated another way, the warning itself can also serve as a direction for use." (Advisory Opn. No. 312, p. 3.) The opinion continued: "Therefore, although the warning quoted in your inquiry does not necessarily convey specific actions to be taken in the use of the product, it does convey information about how the product should be used (steps should be taken to reduce exposure). Accordingly, this office views the statement as a direction for use. It follows, therefore, that signs and the like bearing such warnings are 'accompanying literature containing directions for use' and thus are labeling under FHSA § 2(n)."[19] (*Id.* at p. 4.)

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added.) Thus, it identified point of sale signs as "non-label[s]."

[19] Cotter requests this court to take judicial notice of a letter from

The People respond that the defendant in *Allenby* presented this argument and, rather than ignoring it, the court clearly rejected it. Furthermore, the People contend Advisory Opinion Number 312 is not a long-standing administrative application of the statute and is litigation- inspired because it responds to a request during litigation from defense counsel in *Allenby*. Litigation-inspired opinions have no authority (*Bowen* v. *Georgetown University Hospital* (1988) 488 U.S. 204, 212, 109 S.Ct. 468, 473-474, 102 L.Ed.2d 493), but generally courts have applied this rule only when the administrative agency is a party to the litigation.

The People also claim letters from the general counsel state the March 6, 1991, advisory opinion "did not express a direct opinion on preemption...."[20] Therefore, according to the People, the letter from general counsel is not entitled to deference.

The People's final argument against deferring to the CPSC's advisory opinion is the opinion's interpretation contravenes the language of the statute and regulations. We agree with this assertion and, for the reasons explained fully above, we find the CPSC's interpretation is "'plainly erroneous'" and entitled to no deference. (*Stinson* v. *U.S.* (1993) 508 U.S. 36, 45-46, 113 S.Ct. 1913, 1919, 123 L.Ed.2d 598; *Dix* v. *Superior Court* (1991) 53 Cal. 3d 442, 460, 279 Cal. Rptr. 834, 807 P.2d 1063).

For the foregoing reasons we find point of sale signs pursuant to Proposition 65 do not constitute "directions for use" and are not preempted by the FHSA. We now turn to Cotter's claim of de facto labeling.

CPSC General Counsel Eric A. Rubel dated October 17, 1995, stating Advisory Opinion No. 312 has never been modified, revoked, suspended, or superseded. We grant judicial notice of this letter.

[20] We grant the People's request for judicial notice of letters and other documents from the file of the general counsel of the CPSC. One such letter states "[t]he Commission has not formulated a general view of preemption [of Proposition 65] beyond the express preemption provisions in its various statutes." (Letter dated July 3, 1995, from the general counsel for the CPSC to counsel for Cotter.)

II. Proposition 65 Is Not a De Facto Labeling Statute

Even if point of sale signs are not labels, Cotter argues Proposition 65 can only be implemented by placing labels on a package; therefore, in practice, it is a labeling statute and preempted by the FHSA. Since the question of de facto labeling raises an issue of law and material fact, we independently review the evidence submitted to determine whether it raises a triable issue of material fact. (*Schrader* v. *Scott*, *supra*, 8 Cal. App. 4th 1679, 1684, 11 Cal. Rptr. 2d 433.)

To establish a de facto labeling statute, Cotter must show it can only satisfy the requirements of Proposition 65 by using labels. (*Stratton*, *supra*, 92 F.3d 807, 810 [to find preemption a party must show all possible methods of complying with Proposition 65 conflict with the FHSA].) Cotter cannot establish de facto labeling merely by demonstrating it is difficult or costly to comply. Rather, it must show using point of sale signs is a "physical impossibility." (*See Allenby*, *supra*, 958 F.2d 941, 948- 949 ["[F]or purposes of preemption analysis," the party arguing preemption must show "a physical impossibility of complying" with both Proposition 65 and the federal statute "before succeeding on a claim that Proposition 65 is preempted on this theory."].)

Cotter cites almost no legal authority to support its contention of de facto labeling, but claims point of sale signs cannot be used because they are ineffective and too expensive to implement. Cotter's evidence of "physical impossibility" amounts to little more than submitting a number of conclusions, declarations, and opinions. Interestingly, Cotter fails to explain why, if point of sale signs are so costly and ineffective in communicating a message, manufacturers continue to use them to advertise their goods.

Cotter first argues the warnings required by Proposition 65 "must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure." (Cal. Code Regs., tit. 22, § 12601, subd. (a).) Point of sale signs, he argues, are less effective than product labels in warning consumers. To support this claim he cites a footnote in *King* v. *E.I. Du Pont De Nemours & Co.*, (D. Me. 1992) 806 F. SUPP. 1030, 1037, fn. 4, which was later affirmed in an opinion minus the footnote in *King* v. *E.I.*

DuPont De Nemours and Co., (1st Cir.1993) 996 F.2d 1346. The footnote merely stated "[w]e can see no more effective way to warn potential users of the dangers of a product than by product labels." (*King* v. *E.I. Du Pont De Nemours & Co.*, *supra*, 806 F. SUPP. at p. 1037, fn. 4.) This statement does not establish the ineffectiveness of point of sale signs.

In addition to failing to demonstrate ineffectiveness, Cotter's argument is seriously flawed because a manufacturer does not have to use the best warning method to comply with Proposition 65. The court in *Ingredient Communication Council, Inc.* v. *Lungren* (1992) 2 Cal. App. 4th 1480, 1494, 4 Cal. Rptr. 2d 216 (ICC) confirmed Proposition 65 does not require a manufacturer to use the "'best'" or most effective method, but merely demands a "reasonable" method. Both the court in *ICC*, *supra*, 2 Cal. App. 4th 1480, 1486, 4 Cal. Rptr. 2d 216 and the safe harbor language set forth in the California Code of Regulations (tit. 22 § 12601, subd. (b)(1)(B)) approve of point of sale signs as a reasonable method.[21]

Cotter also claims a manufacturer cannot ensure a retailer will properly post the signs without incurring unacceptable costs to implement the program.[22] In support of this argument, Cotter stated it sent signs to its California members on March 1988 and

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[21] Cotter argues any method other than labeling would not meet the "reasonableness" test of *ICC*, *supra*, 2 Cal. App. 4th at p. 1494, 4 Cal. Rptr. 2d 216. The "reasonableness" test requires the trial court to examine the warning's efficacy and cost before determining whether the warning satisfies Proposition 65. The "reasonableness" test set forth in *ICC*, however, does not apply to point of sale signs. The court in *ICC* limited the "test" to situations in which the trial court had to determine whether "alternative warning methods" — that is, methods outside of the safe harbor warnings — provided a reasonable warning. (*Ibid.*)

[22] Attorneys for the National Paint and Coatings Association (NPCA) filed an amici curiae brief on behalf of Cotter's *de facto* labeling argument. Much of the data on the costs associated with point of sale signs is irrelevant to Cotter's inability to use these signs and outside the record.

January 1990. Moreover, in January 1994, it sent signs again[23] and directed the members to place both signs "close to each of your own paint factory's products." Cotter also submitted deposition testimony of several retailers explaining the problems they had complying with the manufacturer's requests for them to post point of sale warnings.

To counter Cotter's argument, AYS identified numerous paint and/or adhesive manufacturers' complying with Proposition 65 warning signs. Many of True Value Hardware stores did not follow instructions, the People contend, because Cotter did not adequately explain the proper placement of the signs.[24] The People claim once the retailers received explicit instruction about the appropriate location pursuant to the Permanent Injunction, the majority of those deposed testified they understood the directions and properly complied.[25]

In their final argument, the People maintain Cotter cannot argue de facto labeling because it did not attempt to follow the mandate in *ICC*. The court in *ICC* stated a manufacturer must adjust the warning system in light of operational experience and new facts when attempting to comply with Proposition 65. (*ICC*, *supra*, 2 Cal. App. 4th 1480, 1493, 4 Cal. Rptr. 2d 216.) AYS notified Cotter on December 10, 1992, that its stores were not providing

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[23] AYS, an intervener in this action, claims many of these signs did not comply with Proposition 65.

[24] The People contend the directions did not tell retailers to post the signs in front of or next to the spray paints. For example, directions sent January 27, 1992, merely stated: "Signs # 1 and # 2 enclosed should be displayed close to each of your own Paint factory's products."

[25] Cotter insists some retailers did not comply even after being given proper information, establishing manufacturers cannot compel retailers to follow their orders. Cotter, however, misconstrues its burden of proof. It must show it cannot comply and, since most retailers did adhere to Cotter's instructions when given the proper information, compliance seems physically possible. As the People point out, Cotter can use a variety of techniques and incentives to encourage acquiescence among the remainder of the retailers.

warnings for their products containing toluene and Cotter should have taken appropriate steps to remedy the problem. Cotter, the People claim, can exercise a certain level of control over the True Value stores because members of the cooperative must agree to observe Cotter's bylaws, policies, and procedures.[26]

We find the trial court did not err in finding "Proposition 65 does not impose a de facto labeling requirement on Cotter & Company." Cotter has not established the physical impossibility of meeting Proposition 65 warning requirements with point of sale signs. Cotter may ultimately choose to use a label which complies with both Proposition 65 and the FHSA; however, choosing to use a label does not negate the viability of point of sale signs.

CONCLUSION

The warning requirements of Proposition 65 may be satisfied by point of sale signs which are not "directions for use" or labels under the FHSA. The FHSA, therefore, does not preempt Proposition 65. Additionally, Cotter has failed to prove it cannot use point of sale signs and has not established it cannot use point of sale signs to satisfy Proposition 65 warning requirements. Accordingly, we affirm.

KLINE, P.J., and HAERLE, J., concur.

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[26] The People claim Cotter could take additional steps to ensure acquiescence. After an action involving Cotter and improper Proposition 65 warnings for methylene chloride paint strippers, the manufacturer remedied the situation by (1) providing clear directions to the stores for the placement of the signs and (2) requiring each store to return a postcard indicating it had properly posted the warning sign. Cotter followed up with phone calls to those stores not returning the postcard.

APPENDIX B

First Appellate District, Division Two, No. A070904

S061311

IN THE SUPREME COURT OF CALIFORNIA

THE PEOPLE, Respondent [FILED

v. July 9, 1997]

COTTER & COMPANY, Appellant

Appellant's petition for review DENIED.

GEORGE

Chief Justice

APPENDIX C

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF SAN FRANCISCO

PEOPLE OF THE STATE OF CALIFORNIA ex. rrl. DANIEL E. LUNGREN, Attorney General of the State of California,	)	No. 952433 (and consolidated matters 954568, 954993, 957067)
Plaintiffs,	)	
v.	)	ORDER RE SUMMARY ADJUDICATION
THE SHERWIN-WILLIAMS COMPANY, DUPLI-COLOR PRODUCTS COMPANY,	)	
Defendants,	)	[filed Mar. 9, 1995]
and consolidated matters	)	

This matter came on for hearing on February 23, 1995 at 2:00 P.M. in Department 8, the Honorable Stuart R. Pollak presiding. Present were Edward Weil and Susan Fiering, Deputy Attorneys General, for the People of the State of California ("People"), Jeffrey Margulies, Esq. for Cotter & Company ("Cotter"), and Cliff Chanler, Esq. and Syda Kosofky, Esq. for As You Sow.

After full consideration of the evidence, and the separate statements submitted by each party and the authorities submitted by counsel, as well as oral argument by counsel, the Court finds there is no triable issue of material fact as to the Fifth Affirmative Defense asserted in the Answer of Cotter & Company and that summary judgment should be denied to Cotter & Company and a summary adjudication granted to the People. The Court finds that pursuant to the decision of the Ninth Circuit in Chemical Specialties Manufacturers Ass'n. Inc. v. Allenby, 958 F.2d 941 (9th Cir. 1992), Proposition 65 warnings do not constitute cautionary

labeling preempted by the Federal Hazardous Substances Act ("FHSA") as a matter of law.

The Court further finds that, based on the undisputed facts in the record before the Court, Proposition 65 does not impose a de facto labeling requirement on Cotter & Company. The disputes in the record as to the People's facts numbers 25 and 67 and to Cotter's facts numbers 6, 7, 10, 13, 20 and 21 and any dispute as to Cotter's Additional Material Fact in Dispute Number 1 are not genuine and/or are not material to this determination. The remaining undisputed facts stated by the People and Cotter establish that Cotter is not required to provide a warning on the label of its products in order to comply with Proposition 65. Therefore, Proposition 65 does not present a de facto labeling requirement that is preempted by FHSA.

IT IS THEREFORE ORDERED that Cotter's motion for summary judgment is DENIED and the People's motion for summary adjudication of Cotter & Company's Fifth Affirmative Defense is GRANTED and that the final judgment in this action shall, in addition to any other matters determined at trial, award judgment in accordance with the matters so adjudicated.

Dated: 3/9/95

STUART R. POLLAK
JUDGE OF THE SUPERIOR COURT

APPENDIX D

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[Filed June 9, 1995]

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF SAN FRANCISCO

PEOPLE OF THE STATE OF CALIFORNIA ex rel. DANIEL E. LUNGREN, Attorney General of the State of California,	) Case Nos. 952433, 954568, 954993, 957067
Plaintiffs,	) CONSENT JUDGMENT
v.	)
SHERWIN WILLIAMS COMPANY, et al.,	)
Defendants.	)
AND CONSOLIDATED MATTERS	)

1. **INTRODUCTION**

1.0 On September 17, 1993 the People of the State of California ex rel. Daniel E. Lungren ("People"), filed a Complaint for Civil Penalty and Injunctive Relief ("Complaint") in San Francisco County Superior Court, Case No. 954993 against Cotter

& Company ("Cotter) and other defendants. The People's Complaint alleges that Cotter violated provisions of the Safe Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code sections 25249.5 et seq. ("Proposition 65"), and Business and Professions Code sections 17200 et seq. ("Unfair Competition Act"), by knowingly exposing persons to toluene, a chemical known to the State of California to cause birth defects or other reproductive harm, without first providing a clear and reasonable warning to such individuals.

1.1 Cotter is a corporation that employs more than ten persons and manufactures, distributes and sells within the State of California certain paint products and adhesives that contain toluene, a chemical which the State of California placed on its list of chemicals "known to cause reproductive toxicity" pursuant to Health and Safety Code section 25249.9 on January 1, 1991, and thus have been subject to Proposition 65 warning requirements since January 1, 1992. The products covered by this Consent Judgment ("Covered Products") are listed in Exhibits A, B and C hereto.

1.2 Cotter contends that it has complied with consumer product warning requirements under Proposition 65 as it applies to the Covered Products. The People, by their Complaint, contend that Cotter has not taken adequate actions to comply with Proposition 65 as it applies to the Covered Products.

1.3 For purposes of this Consent Judgment the parties stipulate that this Court has jurisdiction over the allegations of violations contained in the Complaint and personal jurisdiction over Cotter as to the acts alleged in the Complaint, that venue is proper in the County of San Francisco and that this Court has jurisdiction to enter this Consent Judgment as a resolution of the allegations contained in the Complaint.

1.4 The parties enter into this Consent Judgment pursuant to a settlement of disputed claims between the parties for the purpose of avoiding prolonged litigation and to insure that the requirements of Proposition 65 are expeditiously carried out. By execution of this Consent Judgment, Cotter does not admit any violations of Proposition 65, the Unfair Competition Act, or any related statutes. Nothing in this Consent Judgment shall be

construed as an admission by Cotter of any fact, issue of law, or violation of law. Nor shall compliance with this Consent Judgment constitute or be construed as an admission by Cotter of any fact, issue of law, or violation of law. However, this paragraph shall not diminish or otherwise affect the obligations, responsibilities, and duties of Cotter under this Consent Judgment.

2. **SETTLEMENT PAYMENT**

2.0 Except as provided in paragraph 2.2 below, within thirty (30) days from the date this Consent Judgment is fully executed by the parties and entered by the Court, Cotter shall pay the sum of $275,000 in settlement of the disputed claims referred to herein with respect to the Covered Products. The money shall be paid as follows:

a. a civil penalty of $155,000 pursuant to Health & Safety Code sections 25249.7(b) and 25192;

b. the sum of $10,000 as a donation to the California Public Health Foundation (CPHF), a tax exempt, charitable corporation organized under the laws of California, for deposit into CPHF's Environmental Health Account, to be used for environmental health activities related to the enforcement of Proposition 65 by the Attorney General, as shall be agreed upon between CPHF and the Attorney General;

c. the sum of $10,000 representing reasonable costs and attorneys fees incurred by the State of California in investigating this matter, prosecuting this action and negotiating this Consent Judgment.

d. the sum of $100,000 to the California Public Health Foundation ("CPHF") as restitution pursuant to the Unfair Competition Act to be used at the discretion of the CPHF either for the "Curriculum Design and Training for Household Hazardous Waste Programs" or the "Professional Education Opportunities for Pediatricians, Public Health Nurses, Home Health Aides Regarding Household Toxics."

2.1 Payment of the amounts specified in paragraph 2.0 a and c above shall be made to the Attorney General of the State of California, 2101 Webster St., 12th Floor, Oakland, CA 94612.

The payments shall note that the payments are made in connection with a settlement of the action and shall be sent to the attention of Deputy Attorney General Susan S. Fiering. Payment of the amounts specified in paragraph 2.0 b above shall be made by delivery of the required amount to CPHF, 2001 Addison Street, Suite 210, Berkeley, California, 94704-1103, attention James B. Simpson, General Counsel. A copy of any payments sent to the CPHF shall be sent to Deputy Attorney General Susan S. Fiering at the address above. Payment of the amounts specified in paragraph 2.0 d shall be made by delivery of the required amount to CPHF at the address above. The payment shall be designated as for the Cotter restitution projects. A copy of any payments shall be sent to Deputy Attorney General Susan S. Fiering at the address above.

3. **INJUNCTIVE RELIEF — CLEAR AND REASONABLE WARNING**

3.0 The Covered Products listed in Exhibit A hereto are subject to a permanent injunction entered by this Court on July 23, 1994 as modified on September 20, 1994. The Covered Products listed in Exhibits B and C hereto ("Covered Products B" and "Covered Products C") were not covered by that injunction and will therefore be subject to the injunctive relief stated herein. The parties hereby agree that the pendency of any appeal by Cotter from the Court's Summary Adjudication Order as set forth in paragraph 5.0 shall not affect or stay Cotter's duty to comply with the terms of the July 23, 1994 Permanent Injunction and September 20, 1994 modification or with the injunctive relief set forth herein.

3.1 As long as any of the Covered Products B continue to contain toluene, Defendant shall provide a clear and reasonable warning under the circumstances and in the manner described in paragraph 3.2 to 3.7 below, that the Covered Product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

3.2 By September 1, 1995, Defendant shall itself take the following actions or shall insure that the manufacturer of the Covered Products B takes the following actions:

- at the point of manufacture, or prior to shipment to California or distribution within California, affix to or print on the product container, cap, label, unit package, or (where the product is too small to receive a warning directly on the container) on the display of such Covered Products that are intended for sale in California the following warning:

> WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm

- Such warning shall be prominently affixed to or printed on each Covered Product B with such conspicuousness, as compared with other words, statements, designs, or devices on the label as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use. The warning shall be at least the same size as the largest of any other safety warnings on the product container and the word "warning" shall be in all capital letters and in bold print. If printed on the label itself the warning shall be contained in the same section of the label that states other safety warnings concerning the use of the product. The Attorney General agrees to review any labeling proposed to be used under this section and advise Defendant as to whether he believes such labeling to comply with this section.

3.3 After September 1, 1995, Defendant shall not ship or cause to be shipped into California for sale in the state and shall not distribute to member retailers for sale in California any such Covered Products B that do not have the warning described in paragraph 3.2 above affixed to or printed on their product container, cap, label, unit package or (where the product is too small to receive a warning directly on the container) on their product display.

3.4 The requirement for product labeling, set forth in paragraphs 3.2 to 3.3 above is imposed pursuant to the terms of this stipulation. The parties recognize that product labeling is not the exclusive method of providing a warning under Proposition 65 and its implementing regulations.

3.5 By June 15, 1995, Defendant shall take the following steps or shall insure that the manufacturer of the Covered B Products takes the following steps:

- send by first class mail a "Proposition 65 Warning Letter," in a form approved by the Attorney General, and the specified enclosures, to the owner or manager for each of Defendant's member retailers.

- After June 15, 1995, send the Proposition 65 Warning Letter and specified enclosures to any new member retailer prior to shipment of any of the Covered Products to such new member retailer.

3.6 The Member Proposition 65 Warning Letter shall contain as enclosures two (2) warning signs printed on 65-pound stock in a size and format to be approved by the Attorney General, to be displayed in front of or next to the Covered Products B so that the warning is visible to the consumer and will be understood to apply only to the affected products. The letter shall also contain as an enclosure a postcard in a form approved by the Attorney General instructing the recipient to sign and return the card to indicate that he/she has received the material and will comply with Proposition 65 by providing the appropriate warnings.

3.7 In the event that the Defendant or the manufacturer does not receive the signed return postcard within twenty days of mailing, Defendant shall cease shipping any Covered Products B to the member retailer until (a) the member retailer subsequently returns the signed postcard to defendant or the manufacturer or (b) the Covered Products B have a Proposition 65 warning affixed to the label or container as set forth in paragraph 3.3 above.

3.8 Until such time as all Covered Products B are labeled pursuant to paragraph 3.2 above, any time a Cotter service representative visits a member retailer, he or she shall take steps to observe whether the member retailer has properly posted the warning signs in front of or next to the Covered Products B so that the warning is visible to the consumer and will be understood to apply only to the Covered Products B. In the event that the service representative determines that the warning signs are not properly posted, he shall post the signs himself and Defendant shall cease

shipping Covered Products B to the member retailer until (a) the member retailer agrees in writing to continue to post the warning signs or (b) the Covered Products B are labeled pursuant to paragraph 3.2 above.

3.9 For the products listed in Exhibit C hereto ("Covered Products C"), the parties agree that the manufacturers of those products have represented and submitted documentation to the Attorney General demonstrating that the products either no longer contain toluene as an intended ingredient or that the containers are labeled with a clear and reasonable warning pursuant to Proposition 65. Based on this representation and the evidence submitted, the Attorney General agrees that these actions constitute compliance with Proposition 65 as to the Covered Products C at this time. In the event that the manufacturers of Covered Products C fail to provide a Proposition 65 warning for Covered Products C as required by law, nothing in this Consent Decree shall diminish or otherwise affect the obligations, responsibilities and duties of Cotter to provide a warning pursuant to Proposition 65.

4. ENTRY OF CONSENT JUDGMENT

4.0 The parties hereby request that the Court promptly enter this Consent Judgment. Provided the Court enters the Consent Judgment, Cotter and People waive their respective rights to a hearing or trial on the allegations of the Complaint except as provided in paragraph 5.

5. APPEAL

5.0 Cotter and the People hereby agree that Cotter shall have no right to appeal from any aspect of this Consent Judgment except that Cotter shall retain the right to appeal from this Consent Judgment only on the grounds that the Court's Summary Adjudication Order denying Cotter's Motion for Summary Judgment and granting the people's Motion for Summary Adjudication on Cotter's Fifth Affirmative Defense, and ruling that Proposition 65 is not preempted by the provisions of the Federal Hazardous Substances Act ("Summary Adjudication Order"), was in error. The parties agree that this is a controlling issue of law in this matter and that determination by the Court of Appeal is appropriate. The parties further agree that if Cotter appeals from

the Court's Summary Adjudication Order, Cotter's duty to comply with this Judgment shall, in all respects, including but not limited to, the payment of prejudgment interest, be the same as with an appeal from a judgment entered after trial, except that, the pendency of the appeal shall not relieve Cotter of its obligations to comply with the terms of the July 23, 1994 Permanent Injunction and the September 20, 1994 modification and with the injunctive relief set forth in paragraph 3.0 herein.

5. MATTERS COVERED BY THIS CONSENT JUDGMENT

5.0 This Consent Judgment constitutes a full and final settlement as to Cotter, its officers, directors, employees, agents and representatives, with respect to all claims, violations, actions, causes of action, damages, penalties, costs or attorneys' fees incurred by the Attorney General's Office, based on alleged violations of Section 25249.6 of Proposition 65 and the Unfair Competition Act, Business and Professions Code Sections 17200 et seq. and any other claim, up to and including the date of execution of this Consent Judgment, brought on behalf of the general public, arising from the failure to provide clear, reasonable, and lawful warnings of exposure to toluene from Covered Products listed in Exhibits A, B and C hereto. This Consent Judgment constitutes a full and final settlement of all such alleged violations, whether committed by Cotter or by an entity within its chain of distribution, including, but not limited to retail sellers of the Covered Products, except that the Consent Judgment does not resolve any alleged violations by manufacturers of any of the products listed in Exhibits B and C hereto.

5.1 Nothing in this Consent Judgment resolves any claim by As You Sow against Cotter for attorneys fees and/or costs pursuant to Code of Civil Procedure section 1021.5.

6. ADDITIONAL ENFORCEMENT ACTIONS: CONTINUING OBLIGATIONS

6.0 The People do not waive any right to take further enforcement actions on any new or additional violations not covered by this Consent Judgment.

7. INCORPORATION OF STIPULATION, SETTLEMENT AGREEMENT AND ORDER AND PERMANENT INJUNCTION INTO CONSENT JUDGMENT

7.0 The Stipulation, Settlement Agreement and Order entered by the Court on November 7, 1994 (copy attached hereto as Exhibit D) is hereby incorporated fully into this Consent Judgment.

7.1 The Permanent Injunction, entered by this Court on July 23, 1994 and the modification entered on September 20, 1994, (copies attached hereto as Exhibit E) are hereby incorporated fully into this Consent Judgment.

8. ENFORCEMENT OF JUDGMENT

8.0 The terms of this Consent Judgment shall be enforced exclusively by the the People and by Cotter. The parties may, by noticed motion or order to show cause before the Superior Court of San Francisco County, giving the notice required by law, enforce the terms and conditions contained herein. In any action brought by the People to enforce this Consent Judgment, the People may seek whatever fines, costs, penalties or remedies as may be provided by law for any violation of the Consent Judgment. Any violation of the terms of the Consent Judgment that also violate Proposition 65 or the Unfair Competition Act or any other laws may subject Cotter to civil penalties under those statutes to be sought in a separate civil action.

9. MODIFICATION OF JUDGMENT

9.0 This Consent Judgment may be modified only upon written agreement of the parties and upon entry of a modified Consent Judgment by the Court thereon, or upon motion of any party as provided by law and upon entry of a modified Consent Judgment by the Court. Any modification of the Stipulation, Settlement Agreement and Order entered by the Court on November 7, 1994 (Exhibit D) shall be as provided in that document.

10. AUTHORITY TO STIPULATE

10.0 Each signatory to this Consent Judgment certifies that he or she is fully authorized by the party he or she represents to enter

into this Consent Judgment and to execute it on behalf of the party represented and legally to bind that party.

11. **RETENTION OF JURISDICTION**

11.0 This Court shall retain jurisdiction of this matter to implement the Consent Judgment.

12. **ENTIRE AGREEMENT**

12.0 This Consent Judgment contains the sole and entire agreement and understanding of the parties with respect to the entire subject matter hereof, and any and all prior discussions, negotiations, commitment and understandings related hereto. No representations, oral or otherwise, express or implied, other than those contained herein have been made by any party hereto. No other agreements not specifically referred to herein, oral or otherwise, shall be deemed to exist or to bind any of the parties.

13. **GOVERNING LAW**

13.0 The validity, construction and performance of this Consent Judgment shall be governed by the laws of the State of California.

IT IS SO STIPULATED:

DATED: May 16, 1995

HAIGHT, BROWN & BONESTEEL

By: /s/
JEFFREY J. MARGULIES
Attorneys for Defendant
Cotter & Company

DATED: May 19, 1995

DANIEL E. LUNGREN, Attorney General of the State of California
THEODORA BERGER
Assistant Attorney General
EDWARD G. WEIL
SUSAN S. FIERING
Deputy Attorneys General

By: /s/
SUSAN S. FIERING
Attorneys for the People of the
State of California

IT IS SO ORDERED, ADJUDGED AND DECREED:

Dated: June 9, 1995

Stuart R. Pollak
JUDGE OF THE SUPERIOR COURT

APPENDIX E

15 U.S.C. § 1261 note

(b)(1)(A) Except as provided in paragraphs (2) and (3), if a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) [15 U.S.C. §§ 1261(p), 1262b)] designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under section 2(p) or 3(b).

* * * * *

(2) The Federal Government and the government of any State or political subdivision of a State may establish and continue in effect a requirement applicable to a hazardous substance for its own use (or to the packaging of such a substance) which requirement is designed to protect against a risk of illness or injury associated with such substance and which is not identical to a requirement described in paragraph (1) applicable to such substance (or packaging) and designed to protect against the same risk of illness or injury if the Federal, State, or political subdivision requirement provides a higher degree of protection from such risk of illness or injury than the requirement described in paragraph (1).

(3)(A) Upon application of a State or political subdivision of a State, the Commission may, by regulation promulgated in accordance with subparagraph (B),exempt from paragraph (1), under such conditions as may be prescribed in such regulation, any requirement of such State or political subdivision designed to protect against a risk of illness or injury associated with a hazardous substance if —

(i) compliance with the requirement would not cause the hazardous substance (or its packaging) to be in violation of the applicable requirement described in paragraph (1), and

(ii) the State or political subdivision requirement (I) provides a significantly higher degree of protection from such risk of illness or injury than the requirement described in paragraph (1), and (II) does not unduly burden interstate commerce.

In determining the burden, if any, of a State or political subdivision requirement on interstate commerce the Commission shall consider and make appropriate (as determined by the Commission in its discretion) findings on the technological and economic feasibility of complying with such requirement, the cost of complying with such requirement, the geographic distribution of the substance to which the requirement would apply, the probability of other States or political subdivisions applying for an exemption under this paragraph for a similar requirement, and the need for a national, uniform requirement under this Act [this chapter] for such substance (or its packaging).

(B) A regulation under subparagraph (A) granting an exemption for a requirement of a State or political subdivision of a State may be promulgated by the Commission only after it has provided, in accordance with section 553(b) of title 5, United States Code [section 553(b) of Title 5, Government Organization and Employees], notice with respect to the promulgation of the regulation and has provided opportunity for the oral presentation of views respecting its promulgation.

* * * * *

15 U.S.C. § 1261(n)

The term "label" means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the case of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (1) on the outside container or

wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (2) on all accompanying literature where there are directions for use, written or otherwise.

15 U.S.C. § 1261(p)

The term "misbranded hazardous substance" means a hazardous substance * * * intended, or packaged in a form suitable, for use in the houshold or by children, if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of this title or if such substance, except as otherwise provided by or pursuant to section 1262 of this title, fails to bear a label —

(1) which states conspicuously (A) the name and place of business of the manufacturer, packer, distributor or seller; (B) the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Commission by regulation permits or requires the use of a recognized generic name; (C) the signal word "DANGER" on substances which are extremely flammable, corrosive, or highly toxic; (D) the signal word "WARNING" or "CAUTION" on all other hazardous substances; (E) an affirmative statement of the principal hazard or hazards, such as "Flammable", "Combustible", "Vapor Harmful", "Causes Burns", "Absorbed Through Skin", or similar wording descriptive of the hazard; (F) precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Commission pursuant to section 1262 of this title; (G) instruction, when necessary or appropriate, for first-aid treatment; (H) the word "poison" for any hazardous substance which is defined as "highly toxic" by subsection (h) of this section; (I) instructions for handling and storage of packages which require special care in handling or storage; and (J) the statement (i) "Keep out of the reach of children" or its practical equivalent, or (ii) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard, and

(2) on which any statements required under subparagraph (1) of this paragraph are located prominently and are in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

16 C.F.R. § 1500.3(c)(9)

In the definition of "label" in section 2(n) of the act [15 U.S.C. § 1261(n)] * * * , a provision stipulates that words, statements, or other information required to be on the label must also appear on all accompanying literature where there are directions for use, written or otherwise. To make this provision more specific, "accompanying literature" is interpreted to mean any placard, pamphlet, booklet, book, sign, or other written, printed, or other graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children.

16 C.F.R. § 1500.14

Products requiring special labeling under section 3(b) of the act.

(a) Human experience, as reported in the scientific literature and to the Poison Control Centers and the National Clearing House for Poison Control Centers, and opinions of informed medical experts establish that the following substances are hazardous:

* * * * *

(3) Products containing * * * 10 percent or more by weight of toluene (also known as toluol) * * * .

* * * * *

(b) The Commission finds that the following substances present special hazards and that, for these substances, the labeling required

by section 2(p)(1) of the act is not adequate for the protection of the public health. Under section 3(b) of the act, the following specific label statements are deemed necessary to supplement the labeling required by section 2(p)(1) of the act:

* * * * *

(3) *Benzene, toluene, xylene, petroleum distillates.* * * *

(ii) Because products containing 10 percent or more by weight of toluene, xylene, or any other substances listed in paragraph (a)(3) of this section may be aspirated into the lungs, with resulting chemical pneumonitis, pneumonia, and pulmonary edema, such products shall be labeled with the signal word "danger," the statement or [sic] hazard "Harmful or fatal if swallowed," and the statement "Call physician immediately."

(iii) Because inhalation of the vapor of products containing 10 percent or more by weight of toluene or xylene may cause systemic injury, such products shall bear the statement of hazard "Vapor harmful" in addition to the statements prescribed in paragraph (b)(3)(ii) of this section.

Cal. Health & Safety Code
§ 25249.6 (1992 & 1997 Supp.)

Required warning before exposure to chemicals known to cause cancer or reproductive toxicity

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual * * * .

Cal. Health & Safety Code § 25249.11 (1992 & 1997 Supp.)

Definitions
For purposes of this chapter:

* * * * *

(f) "Warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable. In order to minimize the burden on retail sellers of consumer products, including foods, regulations implementing Section 25249.6 shall to the extent practicable place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question.

Cal. Code Reg., tit. 22, § 12601

Clear and Reasonable Warnings.

* * * * *

(b) Warnings for consumer products exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed to be clear and reasonable. A "consumer products exposure" is an exposure which results from a person's acquisition, purchase, storage, consumption, or other reasonably forseeable use of a consumer good, or any exposure that results from receiving a consumer service.

(1) The warning may be provided by using one or more of the following methods singly or in combination:

(A) A warning that appears on the product's label or other labeling. The term "label" means a display of written, printed, or graphic matter upon a product or its immediate container. The term "labeling" means any label or other written, printed or graphic matter affixed to or accompanying a products or its container or wrapper.

(B) Identification of the product at the retail outlet in a manner which provides a warning. Identification may be through shelf labeling, signs, menus, or a combination thereof.

* * * * *

(3) The warnings provided pursuant to paragraphs (1)(A) and (1)(B) shall be prominently placed upon a product's label or other labeling or displayed at the retail outlet with such conspicuousness, as compared with other words, statements, designs, or devices in the label, labelign or display as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use.

(4) The warning message must include the following language:

* * * * *

(B) For consumer products that contain a chemical known to the state to cause reproductive toxicity:
"WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

Supreme Court, U.S.
FILED
NOV 6 1997

No. 97-615

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1997

TRUSERV CORPORATION, *Petitioner*,

v.

THE PEOPLE OF THE STATE OF CALIFORNIA, EX REL. DANIEL E. LUNGREN, ATTORNEY GENERAL, AND AS YOU SOW, *Respondents*.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

RESPONDENT PEOPLE OF THE STATE OF CALIFORNIA'S BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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88 pp

QUESTION PRESENTED

California's Proposition 65 requires that businesses that expose individuals to certain toxic chemicals provide "clear and reasonable" warnings. Warnings may be provided in any of several ways, one of which is through the use of point-of-sale shelf signs that contain the following language:

> **WARNING:** This product contains a chemical known to the state of California to cause birth defects or other reproductive harm.

The Federal Hazardous Substances Act preempts "cautionary labeling requirements" imposed by states. "Label" includes accompanying literature, but only if that accompanying literature contains directions for use.

This case raises a narrow question -- whether a point-of-sale shelf sign containing the language, "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm," is a direction for use and therefore a form of "labeling" preempted by the FHSA.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
OPINION BELOW	1
JURISDICTION	1
STATUTORY AND REGULATORY PROVISIONS	2
STATEMENT OF THE CASE	3
A. Statutory Framework	3
1. Proposition 65	3
2. The Federal Hazardous Substances Act	4
B. The Prior Litigation	6
C. The Court of Appeal Decision	7
REASONS FOR DENYING THE PETITION	8
I. THE *COTTER* DECISION INVOLVES A UNIQUE STATE LAW AND A NARROW QUESTION OF STATUTORY INTERPRETATION, WHICH DOES NOT PRESENT NATIONWIDE ISSUES MERITING THIS COURT'S REVIEW	10
II. THE *COTTER* DECISION IS CORRECT	11

TABLE OF CONTENTS, CONT'D

	Page
A. The Statute is Clear: Only Labeling Requirements are Preempted	11
B. The FHSA Preempts Accompanying Literature Only When it Contains Directions for Use	12
C. A Proposition 65 Warning is Not a Direction for Use	14
D. The Principles that the Court of Appeal Derived from *Medtronic* are Accurate and the Result would be the Same, even Independent of the Medtronic Analysis	15
III. THE COTTER DECISION DOES NOT CONFLICT WITH THE DECISIONS OF OTHER COURTS	17
A. The *Cotter* Decision Does Not Conflict with Decisions Holding that the FHSA Preempts Common Law Failure to Warn Claims that Directly Challenge the Adequacy of the Label	17
B. The Cotter Decision Does Not Conflict with Decisions Holding that FIFRA Preempts Common Law Failure to Warn Claims	19

TABLE OF CONTENTS, CONT'D

	Page
C. The Court of Appeal's Reasoning that FIFRA and FHSA Preemption are not Absolutely Identical is Correct and is Consistent with the Decision of This and Other Courts	22
D. The Court of Appeal's Distinction Between Common Law Failure to Warn Claims and Proposition 65 is Correct and Does Not Conflict with This Court's Decisions	25
CONCLUSION	26

TABLE OF AUTHORITIES

Page

Cases

American Meat Institute v. *Ball*
424 F.Supp. 758 (W.D. Mich. 1976) 12, 22

Arkansas-Platte & Gulf Partnership
v. *Van Waters & Rogers, Inc.*
981 F.2d 1177 (CA10)
cert. denied, 510 U.S. 813 (1993) 20, 21

Beyrle v. *Finneron*
229 A.D.2d 1010, 645 N.Y.S.2d 192
(A.D. 4 Dept. 1996) 18

Bice v. *Leslie's Poolmart, Inc.*
39 F.3d 887 (CA8 1994) 20

Busch v. *Graphic Color Corp.*
169 Ill.2d 325, 662 N.E.2d 397 (Ill.)
cert. denied, 136 L.Ed.2d 18, 117 S.Ct. 55 (1996) 18, 23

Canty v. *Ever-Last Supply Co.*
296 N.J. Super. 68, 685 A.2d 1365
(N.J. Super.L 1996) 1

Chemical Specialty Manufacturers Association v. *Allenby*
744 F.Supp. 934 (N.D. Cal. 1990) 6, 22

Chemical Specialty Manufacturers Association v. *Allenby*
958 F.2d 941 (CA9)
cert. denied,
Chemical Speciality Manufacturers Association v. *Book*
506 U.S. 825 (1992) 2, 6, 7, *passim*

TABLE OF AUTHORITIES, CONT'D

Page

Cases

Chevron, U.S.A., Inc.
v. *Natural Resources Defense Council, Inc.*
467 U.S. 837 (1984) 15

Cipollone v. *Liggett Group, Inc.*
505 U.S. 504 (1992) 11, 16, 17, *passim*

Comeaux v. *National Tea Co.*
81 F.3d 42 (CA5 1996) (per curiam) 18, 23

Duplin v. *Whink Products Co.*
1994 WL 197612 (Conn.Super.Ct., May 2, 1994) 19

Ferebee v. *Chevron Chem. Co.*
736 F.2d 1529 (CA D.C.)
cert. denied, 469 U.S. 1062 (1984) 20

Gade v. *National Solid Wastes Management Ass'n*
505 U.S. 88 (1992) 24

Goodwin v. *Bacon*
127 Wash.2d 50, 896 P.2d 673 (Wash. 1995) 20

Grocery Mfrs. of America v. *Gerace*
755 F.2d 993 (CA2)
cert. denied, 474 U.S. 820 (1985) 22

Jenkins v. *Amchem Prods., Inc.*
256 Kan. 602, 886 P.2d 869 (Kan. 1994)
cert. denied, 116 S.Ct. 80 (1995) 20

TABLE OF AUTHORITIES, CONT'D

Cases	Page
Jenkins v. *James B. Day & Co.* 69 Ohio St.3d 541, 634 N.E.2d 998 (Ohio 1994)	19, 23
King v. *E.I. DuPont De Nemours & Co.* 806 F.Supp. 1030 (D.Me. 1992) *aff'd* 996 F.2d 1346 (CA1 1993)	21, 23
King v. *E.I. Dupont De Nemours & Co.* 996 F.2d 1346 (CA1) *cert. dismissed*, 510 U.S. 985 (1993)	20
Lee v. *Boyle* 792 F.Supp. 1001 (W.D. Pa. 1992)	18
MacDonald v. *Monsanto Co.* 27 F.3d 1021 (CA5 1994)	20
Malone v. *White Motor Corp.* 435 U.S. 479, 98 S.Ct. 1185, 55 L.Ed.2d 443 (1978)	24
Medtronic, Inc. v. *Lohr* 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996)	9, 10, 15, *passim*
Moss v. *Parks* 985 F.2d 736 (CA4) *cert. denied*, 509 U.S. 906 (1993)	18, 23
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TABLE OF AUTHORITIES, CONT'D

Page

Cases

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874 F.2d 115 (CA2 1989) 21

Papas v. *Upjohn*
985 F.2d 516 (CA11)
cert. denied, 510 U.S. 913 (1993) 20, 23

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53 Cal.App.4th 1373;
62 Cal.Rptr.2d 368 (1997) 1, 7, 8, *passim*

Salazar v. *Whink*
881 P.2d 431 (Colo.Ct.App.)
cert. denied, 1994 Colo. LEXIS 793 (1994) 18

Shaw v. *Dow Brands, Inc.*
994 F.2d 364 (CA7 1993) 20

State ex rel Jones Chemicals Inc. v. *Seier*
871 S.W.2d 611 (Mo.App. E.D. 1994) 18

Taylor AG Indus. v. *Pure-Gro*
54 F.3d 555 (CA9 1995) 20, 23

Wallace v. *Parks Corp.*
212 A.D.2d 132, 629 N.Y.S.2d 570
(A.D. 4 Dept. 1995) 18

Worm v. *American Cyanamid Co.*
5 F.3d 744 (CA4 1993) 20, 23

TABLE OF AUTHORITIES, CONT'D

	Page
Constitutional Provisions	
Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65")	i, 2, 3, *passim*
Statutes	
7 U.S.C. § 136(p)(2)	23
15 U.S.C.	
§§ 1261 et seq.	4
§§ 1261-1277	2
§ 1261 note	5, 11, 13
§ 1261(n)	5, 16, 23
§ 1261(p)	4, 5, 13
§ 1262(b)	5, 13
21 U.S.C. § 678	22
28 U.S.C. § 1257(a)	1
Cal. Health & Safety Code §§ 25249.5 *et seq.*	2
Cal. Health & Safety Code § 25249.6	3
Cal. Health & Safety Code § 25249.10	3
Cal. Health & Safety Code § 25249.10(b)	4
Cal. Health & Safety Code § 25249.11(f)	3

TABLE OF AUTHORITIES, CONT'D

	Page
Regulations	
15 C.F.R.	
§ 1500.3(c)(9)	14
§ 1500.82(a)	14
16 C.F.R.	
§ 1500.1 et seq.	2
§ 1500.3(c)(9)	5
§ 1500.14(b)	13
§ 1500.15	14
§ 1500.121(c)(6)	5
§ 1500.125	6
22 C.C.R.	
§§ 12000 et seq.	2, 4
§ 12601(b)	3
§ 12601(b)(4)(B)	4
Other Authorities	
H.R. Rep. No. 2166, 89th Cong., 2d Sess. 6, *reprinted in* 1966 U.S. Code Cong. & Admin. News, pp. 4095, 4097, 4100	4, 12
S.R. No. 94-251, 94th Cong., 2d Sess., *reprinted in* 1976 U.S. Code Cong. & Admin. News, p. 1004	5

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1997
No. 97-615

TRUSERV CORPORATION, *Petitioner*,

v.

THE PEOPLE OF THE STATE OF CALIFORNIA,
EX REL. DANIEL E. LUNGREN, ATTORNEY GENERAL,
AND AS YOU SOW, *Respondents*.

OPINION BELOW

The California Court of Appeal's opinion is reported at 53 Cal.App.4th 1373, 62 Cal. Rptr.2d 368. The California Supreme Court's order denying review is unreported.

JURISDICTION

The California Court of Appeal entered judgment on March 31, 1997. The California Supreme Court denied review on July 9, 1997. Petitioners have invoked the jurisdiction of this Court under 28 U.S.C. section 1257(a).

STATUTORY AND REGULATORY PROVISIONS

The relevant provisions of the Federal Hazardous Substances Act, 15 U.S.C. sections 1261-1277, and its implementing regulations, 16 CFR sections 1500.1 et seq., and the relevant provisions of Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, California Health & Safety Code sections 25249.5 et seq., and its implementing regulations, 22 California Code of Regulations sections 12000 et seq., are set forth in the Appendix.

STATEMENT OF THE CASE

For the second time, this Court has been asked to decide whether Proposition 65 point-of-sale signs are directions for use and are therefore labels preempted by the Federal Hazardous Substances Act. The Court first faced this question in 1992 when it denied certiorari to review the Ninth Circuit decision in *Chemical Specialty Manufacturers Association, v. Allenby*, 958 F.2d 941 (CA9), *cert. denied, Chemical Specialty Manufacturers Association v. Book*, 506 U.S. 825 (1992). The identical issue has now found its way through the state system, with the same result: The state trial and appellate courts have concluded that a Proposition 65 point-of-sale sign is not a label preempted by the FHSA. Because the question involves a statute that is unique to California, the narrow issue presented has been put to rest and will not likely arise again, in either state or federal court, unless this Court decides to take review.

A. Statutory Framework

1. Proposition 65

Proposition 65 is a "right to know" initiative passed by a vote of the People of the State of California in November, 1986. The portion of the statute at issue here is the warning requirement contained in California Health and Safety Code ("Cal. Health & Saf. Code") section 25249.6:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . .

The statute provides that the warning may be given by general methods such as "labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." *Id.*, § 25249.11(f). Warnings are not required where the party causing the exposure can show that the exposure causes no significant risk or will have no observable effect. *Id.* § 25249.10.

Implementing regulations promulgated by the State further identify certain methods of providing warnings for consumer products that are deemed to comply with the statute (i.e., "safe harbors"), but also allow businesses to use other warning methods that are "clear and reasonable." 22 California Code of Regulations ("Cal. Code Regs.") § 12601(b). For consumer products,the "safe harbors" include (1) product labeling and (2) "shelf labeling, signs, menus or a combination thereof" containing specified language. *Id.*[1/]

---

1. All types of shelf labeling signs or any other material

For reproductive toxins the safe harbor language is "**WARNING**: This product contains a chemical known to the state of California to cause birth defects or other reproductive harm." 22 Cal. Code Regs. § 12601(b)(4)(B).

Toluene, the chemical at issue in this case, was listed as a reproductive toxin on January 1, 1991. 22 Cal. Code Regs. § 12000. Exposures to toluene were therefore subject to the warning requirement as of January 1, 1992. Cal. Health & Saf. Code § 25249.10(b).

2. The Federal Hazardous Substances Act

The Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. §§ 1261 et seq., requires that certain consumer products that are "hazardous substances" must provide cautionary labels on their products. 15 U.S.C. § 1261(p). In 1966, Congress adopted what it described as a "limited" preemption amendment intended to protect manufacturers from the need to label each product specially to comply with different state and local requirements. H.R. Rep. No. 2166, 89th Cong., 2d Sess. 6, *reprinted in* 1966 U.S. Code Cong. & Admin. News, p. 4095, 4097, 4100.

In 1976, Congress narrowed this provision, limiting preemption to instances where there is a federal cautionary labeling requirement in effect designed to protect against a risk of illness or injury, and a state imposes a different cautionary labeling requirement for the same risks:

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displayed with the product in the store, as distinguished from package labeling, will be referred to herein as "point-of-sale" signs.

> . . . if a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(b) or 3(b) [15 U.S.C. sections 1261(p) or 1262(b)] designed to protect against a risk of illness or injury associated with the substance, no State . . . may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under 2(p) or 3(b).

15 U.S.C. § 1261 note.

In adopting this preemption provision, Congress specifically rejected the idea of imposing uniform national labeling requirements. *See* S.R. No. 94-251, 94th Cong., 2d Sess., *reprinted in* 1976 U.S. Code Cong. & Admin. News 1004.

The FHSA does not define the term "cautionary labeling requirement." It does, however, define "label" as "a display of written, printed or graphic matter upon the immediate container of any substance. . ." It is beyond dispute that a point-of-sale sign is not a label in the narrow sense of that definition under the FHSA, but the definition also provides that a requirement that information appear on the label is not complied with unless the information also appears "on all accompanying literature where there are directions for use, written or otherwise." 15 U.S.C. section 1261(n). By regulation, the CPSC similarly defined "accompanying literature" to include any written material "that provides direction for use." 16 CFR § 1500.3(c)(9).[2/]

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2. *See also* 16 CFR section 1500.121(c)(6) ("Where literature accompanying the package of a hazardous

Thus, the FHSA's labeling requirements extend to accompanying literature only when that literature provides directions for use.

When the preemption provision of the FHSA is viewed in conjunction with the statutory and regulatory definitions of "label" and "accompanying literature," it is clear that the FHSA preempts state warnings only when they are imposed on the label itself or on accompanying literature containing directions for use.

B. The Prior Litigation

The arguments advanced by TruServ Corporation, formerly Cotter & Company ("Cotter") are not new.[3/] In 1989, the Chemical Specialties Manufacturers Association ("CSMA") sued the State of California in federal court, alleging that Proposition 65 was preempted by the FHSA. The federal district court determined that Proposition 65 point-of-sale signs do not contain directions for use, are not labeling under the FHSA, and therefore are not preempted. *Chemical Specialties Manufacturers Association ("CSMA") v. Allenby*, 744 F.Supp. 934 (N.D. Cal. 1990). The Ninth Circuit Court of Appeals unanimously affirmed in *CSMA v. Allenby*, 958 F.2d 941 (1992). CSMA filed a petition for

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substance has directions for use, written or otherwise, section 2(n) of the Act requires the literature to bear cautionary labeling"; 16 CFR section 1500.125 ("When any accompanying literature includes or bears any directions for use (by printed word, picture, design or combination thereof), such placard, pamphlet, booklet, book, sign, or other graphic or visual device shall bear all the information required by section 2(p) of the act. . .")

3. For ease of reference, the People will continue to refer to both Cotter & TruServ Corporation as "Cotter."

writ of certiorari, raising the same argument that is presented here. Petition for Writ of Certiorari No. 91-1957 at 25-28. This Court denied the petition on October 5, 1992. *CSMA v. Book*, 506 U.S. 825 (1992).

In 1993, the People sued Cotter under Proposition 65, alleging that Cotter failed to warn of exposure to toluene, a reproductive toxin, from its spray paints. Cotter argued that Proposition 65 was preempted by the FHSA. The trial court, relying on the Ninth Circuit's *Allenby* decision, ruled that Proposition 65 could be complied with through point-of-sale signs, that the safe harbor warning language was not a direction for use, and therefore the point of sale signs were not labeling as defined by the FHSA and were not preempted. Cotter appealed and the Court of Appeal unanimously affirmed the decision of the trial court. *People v. Cotter & Company*, 53 Cal.App.4th 1373. The California Supreme Court denied review on July 9, 1997. 1997 Cal. LEXIS 4215 (1997).

C. The Court of Appeal Decision

The California Court of Appeal began with the well-accepted presumption that the traditional police powers of the state are not to be displaced by federal law unless that is the clear and manifest intent of Congress. *Cotter*, 53 Cal.App.4th at 1380. With this presumption as a backdrop, the Court of Appeal came to the same simple and inescapable conclusions reached by both federal courts and the state trial court -- that the FHSA preempts only labeling requirements; that accompanying literature is considered part of the product labeling only when that literature contains directions for use; and that Proposition 65 point-of-sale warning signs do not contain directions for use, are not labeling under the FHSA and therefore are not preempted. *Id.* at 1386-1393. The Court reasoned that if Congress had wanted to preempt all accompanying literature and all

warnings, as Cotter argued, it could have so specified. *Id.* at 1387.[4]

REASONS FOR DENYING THE PETITION

Cotter urges this Court to grant certiorari to resolve perceived conflicts concerning preemption of common law claims under the FHSA, the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") and the Medical Device Amendments to the Food, Drug and Cosmetics Act. Far from being an ideal vehicle to resolve the alleged conflicts, this case presents a narrow and limited question of statutory definition that has little implication to the issues raised by Cotter.

The FHSA, which regulates household toxins, preempts only state imposed "cautionary labeling requirements." The critical question therefore is whether a Proposition 65 point-of-sale sign is a state imposed cautionary labeling requirement.

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4. The *Cotter* Court also addressed a second, highly fact-specific, issue -- whether Cotter had shown that it was impossible for it to comply with Proposition 65 through the use of point-of-sale signs. The Court concluded that the trial court did not err in concluding that Cotter had failed to meet its burden of proof in this regard and therefore Proposition 65 did not present a de facto labeling requirement that was preempted by federal law. *Cotter*, 53 Cal.App.4th at 1396. This issue has not been raised in this Petition. Thus, it is undisputed that Cotter can comply with Proposition 65 without making any changes to the label on its products.

Ignoring the express language of the statute, Cotter argues that any warning requirement, whether it is a labeling requirement or not, is preempted, simply because any additional warning implicitly challenges the adequacy of the label. Cotter suggests therefore that not only are label warnings preempted, but so too are letters, phone calls to customers or newspaper ads. Petition for Writ of Certiorari ("Petition") at 26. In effect, Cotter argues that Congress has implicitly occupied the entire field of warnings in whatever channel of communication.

Cotter's argument is directly contrary to the express language of the statute, which preempts only **labeling** requirements. While Congress certainly could have occupied the field and preempted all warnings in whatever channel of communication, it simply did not do so.

Furthermore, there is no conflict between the result reached by the Court of Appeal and the decisions of numerous courts concerning preemption of common law failure to warn claims under both the FHSA and FIFRA. Quite to the contrary, while the courts have consistently found preemption of common law failure to warn claims that directly challenge the adequacy of the label, they have declined to find preemption of state statutory warning requirements that are imposed outside of and without regard to the label.

Finally, the Court of Appeal's application of *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) is correct, but even if it were not, this case does not merit review. The result reached by the Court of Appeal would be the same, even independent of the *Medtronic* analysis. There simply is no basis under the FHSA to hold, as Cotter urges, that Congress implicitly occupied the whole field of warnings, even while explicitly preempting only "labeling requirements."

I.

THE *COTTER* DECISION INVOLVES A UNIQUE STATE LAW AND A NARROW QUESTION OF STATUTORY INTERPRETATION, WHICH DOES NOT PRESENT NATIONWIDE ISSUES MERITING THIS COURT'S REVIEW

This case raises a peculiarly narrow question -- whether a point of sale sign containing the language "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm" is a direction for use and therefore a form of "labeling" preempted by the FHSA. The question will not likely arise again, because Proposition 65 is a California statute, and the issue has been resolved both by the Ninth Circuit and by the lower state courts.

Ignoring the specifics of the case, Cotter focuses only on the broadest of generalities, arguing that the Court should grant review because the FHSA applies to hundreds of thousands of products; because many other statutes preempt labeling; and because it alleges there is widespread confusion with this Court's decision in *Medtronic*. Petition at 21-23.

The focus on generalities blurs the narrow scope of the *Cotter* decision, a decision that deals with a single state statute and a narrow definitional question under the FHSA.

II.

THE *COTTER* DECISION IS CORRECT

A. The Statute is Clear: Only Labeling Requirements are Preempted

Cotter's argument is simple. It asserts that any state imposed cautionary requirement, in any channel of communication, whether labeling or not, is preempted because additional cautionary statements implicitly challenge the adequacy of the label warning. In effect, Cotter asks the Court to ignore the clear language of the FHSA which preempts only "cautionary labeling requirements," 15 U.S.C. § 1261 note, and to find implied occupation of and preemption of the entire field of warnings.

This argument is wrong. As stated by this Court in *Cipollone v. Liggett Group, Inc.* 505 U.S. 504, 517 (1992), "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." In *Cipollone*, where the act in question preempted only state laws with respect to "advertising or promotion" of cigarettes, state law duties to disclose facts through "channels of communication other than advertising or promotion" were not preempted." *Id.* at 528.

Here too, where the FHSA preempts only cautionary labeling requirements, state law duties to warn in channels of communication other than labeling are not preempted.

Furthermore, congressional concern with minimizing the burdens on manufacturers from having to prepare multiple product labels,[5] is not associated with point-of-sale warnings, which can be prepared and distributed separately to meet the requirements of individual states. Thus, there is nothing in the legislative history of the FHSA that indicates that Congress intended to prohibit a state from communicating information to its citizens in channels other than labeling in order to enable them to make informed purchasing decisions. *Cf. American Meat Institute v. Ball*, 424 F.Supp. 758, 766 (W.D. Mich. 1976) (reaching same conclusion concerning the Federal Wholesome Meat Act).

Finally, while the result is not what Cotter may have wanted, it is the only result that is consistent with the plain language of the statute. Congress did not accidentally choose the "cautionary labeling requirements" language for the preemption provision to the statute. It used the language deliberately and it is this language which circumscribes the scope of the limited preemption granted by Congress. Thus, Cotter's quarrel is with Congress, not with the interpretations of the courts and it should not be permitted to circumvent the intent of Congress and seek from the courts what it could not obtain from Congress.

B. The FHSA Preempts Accompanying Literature Only When it Contains Directions for Use

Cotter next argues that, even if the statute means what it says, and preempts only "labeling" requirements

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5. H.R. Rep. No. 2166, 89th Cong., 2d Sess. 6, *reprinted in* 1966 U.S. Code Cong. & Admin. News, pp. 4095, 4097, 4100.

rather than all warnings, the Court of Appeal should have defined labeling to include all accompanying literature, not just accompanying literature that contains directions for use. Understandably dissatisfied with the narrow language used by Congress in the FHSA, the only statute at issue in this case, Cotter attempts to turn this Court's attention to language used in other statutes such as the Food Drug and Cosmetics Act and FIFRA, that define labeling to include all accompanying literature, not just accompanying literature that contains directions for use. Petition at 28.

There is no need to look beyond the FHSA and its implementing regulations, however. While the FHSA does not define "labeling" specifically, it shows an awareness of the distinction between package labeling and accompanying literature and makes clear that the FHSA regulates accompanying literature as labels only when that literature contains directions for use. *See* 15 U.S.C. § 1261 note.

Furthermore, rather than treating the term "labeling" as distinct from "label," as Cotter suggests, the FHSA and its implementing regulations use the terms label and labeling interchangeably. For example, the preemption provision at issue here, section 1261 Note, refers to "cautionary **labeling** requirements under section 2(p) or 3(b) [15 U.S.C. §§ 1261(p), 1262(b)]." Section 1261(p) refers both to the "packaging or **labeling** of" a substance and to a substance that "fails to bear such **label**." Section 1262(b) refers to "additional **label** requirements" and a substance that "fails to bear a **label**." (emphasis added in all) The regulations similarly use the terms interchangeably.[6/]

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6. *See* 16 C.F.R. § 1500.14(b) (Commission finds that for certain substances "**labeling** required by section 2(p) of the act is not adequate. . . the following specific **label** statements are deemed necessary to supplement the **labeling**

In the end, Cotter's argument is futile. Even if the Court were to accept Cotter's argument that labeling should be defined to include all accompanying literature, the term "accompanying literature" is itself defined narrowly in the regulations to include only literature that provides directions for use. 15 C.F.R. section 1500.3(c)(9) ("'accompanying literature' is interpreted to mean any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device **that provides directions for use**, written or otherwise. . . .") (emphasis added). Thus, even if all accompanying literature is preempted, a Proposition 65 point-of-sale sign is not considered accompanying literature, according to the regulatory definition, because it does not contain directions for use, and therefore is not preempted.

C. A Proposition 65 Warning is Not a Direction for Use

Finally, driven yet one more step back into the express language of the statute, Cotter argues that, even if the FHSA preempts only warnings in accompanying literature containing directions for use, a Proposition 65 point-of-sale sign is an implied direction for use and therefore is preempted. Cotter relies on a March, 1991 advisory opinion from the general counsel of the Consumer Product Safety Commission ("CPSC") stating that the Proposition 65 safe harbor warning should be considered a

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required by section 2(p)(1) of the act. . . ." (emphasis added); 16 C.F.R. section 1500.15 "**Labeling** of fire extinguishers"; substance, when used according to "**label** directions" shall bear the following "**labeling**"; 15 C.F.R. § 1500.82(a) ("Exemption from full **labeling** and other requirements"; "Any person who believes a particular hazardous substance. . . should be exempted from full **label** compliance. . . ." (emphasis added in all).

label under the FHSA, because the warning, while not an express direction for use, implies that "steps should be taken to minimize or eliminate exposure." Advisory Opinion No. 312 at 4.[7]

The Court of Appeal, like the Ninth Circuit, the federal district court and the state trial court before it, did not simply decide that another reading of the FHSA was "more reasonable" than the CPSC general counsel's reading. It decided that the general counsel's interpretation was contrary to the language of the statute as well as to the strong presumption against preemption of state health and safety statutes and was therefore entitled to no deference. *Cotter*, 53 Cal.App.4th at 1393. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.* 467 U.S. 837, 842 (1984) (agency interpretation that is "arbitrary, capricious, or manifestly contrary to the statute. . . ." is not entitled to deference). This conclusion, reached by eight different judges, is correct. By conflating warnings and directions for use, the CPSC opinion ignores the clear language of the statute, which distinguishes between warnings and directions for use, and impermissibly broadens the scope of preemption to include warnings on all accompanying literature whether the accompanying literature contains directions for use or not.

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7. The CPSC letter was previously presented to this Court in June of 1992 in the CSMA's Petition for Writ of Certiorari (No. 91-1957). CSMA made the same argument as Cotter makes here, i.e., that the court, (in that case the Ninth Circuit) wrongly declined to follow the CPSC interpretation. CSMA Petition at 27-29.

D. The Principles that the Court of Appeal Derived from *Medtronic* are Accurate and the Result would be the Same, even Independent of the Medtronic Analysis

Cotter also argues that review is warranted because the Court of Appeal wrongly applied *Medtronic's* general/specific distinction outside of the context of the Medical Device Amendments. Petition at 29-30. The Court of Appeal's application of *Medtronic* to this case was both limited and correct. The Court of Appeal first looked to the exact words of the FHSA, noting that "Congress chose to restrict the definition of a label to include accompanying literature only when that material contains 'directions for use.' (15 U.S.C. § 1261(n).)" *Cotter*, 53 Cal.App.4th at 1387. It went on to note that "if Congress wanted preemption under the FHSA to apply to all accompanying literature with 'implied' directions for use, as Cotter argues, Congress could have specified that." *Id.* The Court of Appeal further stated that it would interpret the words in the preemption provision narrowly and concluded that, based on the generality of the FHSA, point of sale signs "are unlikely to interfere with the federal government's objectives." 53 Cal.App.4th at 1388.

This analysis is consistent with the entire realm of supremacy clause jurisprudence, in particular with the two fundamental principles of preemption analysis, first that the presumption against preemption of state police powers mandates a narrow interpretation of preemption provisions, *Medtronic*, 116 S.Ct. at 2250, *Cipollone*, 505 U.S. at 518, and second, that preemption analysis requires a careful comparison to determine whether "a particular state requirement threatens to interfere with a specific federal interest." *Medtronic*, 116 S.Ct. at 2257; *Cipollone*, 505 U.S. at 524-530 (performing detailed comparison between

each of the state requirements and the federal interest at issue as expressed in the preemption provision of the statute).

Finally, the fact that the *Cotter* court drew general lessons from *Medtronic*, while other courts have declined to do so, does not present a conflict that merits review in this case. Even if the Court of Appeal were incorrect in its application of the *Medtronic* reasoning, its ultimate conclusions -- that Proposition 65 point of sale signs are not cautionary labeling requirements and are not preempted by the FHSA -- are inescapable and are consistent with *Cipollone* and all of the relevant case law.

III.

THE COTTER DECISION DOES NOT CONFLICT WITH THE DECISIONS OF OTHER COURTS

Focusing on generalities and ignoring the specific and narrow ruling of this case, Cotter argues that the Court of Appeal's decision conflicts with decisions of other courts. These "conflicts" are illusory.

A. The *Cotter* Decision Does Not Conflict with Decisions Holding that the FHSA Preempts Common Law Failure to Warn Claims that Directly Challenge the Adequacy of the Label

Far from being "deeply divided," as Cotter suggests, the case law concerning preemption of common law warning claims is consistent. Of the FHSA cases cited by Cotter, all were based on common law failure to warn claims that directly challenged the adequacy of the label and,

with one somewhat ambiguous exception, all concluded that such claims were preempted by the FHSA.[8/]

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8. *See, Comeaux v. National Tea Co.*, 81 F.3d 42, 43 (CA5 1996) (per curiam) (only issue raised on appeal was adequacy of warnings provided by product); *Moss v. Parks*, 985 F.2d 736, 740 (CA4) *cert. denied*, 509 U.S. 906 (1993) ("In actions such as the present one, if the plaintiff requests a label that is 'more elaborate or different' than the one required by the FHSA and its regulations, the claim is preempted.") *Lee v. Boyle*, 792 F.Supp. 1001, 1007-08 (W.D. Pa. 1992) (common law claims preempted because they mandate different labeling requirements than the FHSA); *Salazar v. Whink*, 881 P.2d 431, 432-33 (Colo.Ct.App.), *cert. denied*, 1994 Colo. LEXIS 793 (1994) (issue concerned adequacy of warning on product; state common law duty to warn is nothing more than a duty to label a product to provide information); *Busch v. Graphic Color Corp.*, 169 Ill.2d 325, 662 N.E.2d 397, 401, 405-06 (Ill.), *cert. denied*, 136 L.Ed.2d 18, 117 S.Ct. 55 (1996) (claim preempted because plaintiff argued that label warning was insufficient and that additional warnings needed to be included on the label) *State ex rel Jones Chemicals Inc. v. Seier*, 871 S.W.2d 611, 614 (Mo.App. E.D. 1994) (FHSA preempts state common law failure to warn claims based on the adequacy of the label to the extent that those claims would create labeling requirements different from under the FHSA); *Canty v. Ever-Last Supply Co.*, 296 N.J. Super. 68, 685 A.2d 1365, 1374 (N.J. Super.L 1996) ("Where a plaintiff's claim seeks to hold a manufacturer responsible for failing to provide warning labels which are not identical to those required under the FHSA, that claim is preempted."); *Beyrle v. Finneron*, 229 A.D.2d 1010, 645 N.Y.S.2d 192, 193 (A.D. 4 Dept. 1996) (claim alleging that product label did not contain adequate warnings); *Wallace v. Parks Corp.*, 212 A.D.2d 132, 629 N.Y.S.2d 570, 573-74 (A.D. 4 Dept.

Regardless of whether these courts correctly found preemption of state tort laws, none of the cases addressed the specific question here, i.e., whether the FHSA preempts state statutory non-label warning requirements. While this Court may someday need to face the question of whether the preemptive language of the FHSA was intended to preempt state common law tort claims, it would be ill-advised to do so in a case that involves neither tort law nor a product label.

B. The Cotter Decision Does Not Conflict with Decisions Holding that FIFRA Preempts Common Law Failure to Warn Claims

Cotter next suggests that the Court should review this case so that it can resolve perceived conflicts regarding preemption under FIFRA, an entirely different statute. Again, this case is a poor vehicle, at best, for such an excursion.

1995) (allegations that warnings on container were inadequate; prevailing rule is that plaintiff's claims are preempted only to the extent they require a showing that label and package should have included additional or different warnings); *Jenkins v. James B. Day & Co.*, 69 Ohio St.3d 541, 634 N.E.2d 998, 1004-05 (Ohio 1994) (no preemption of common law claim for failure to provide warning where the plaintiff alleges that label failed to comply with FHSA).

The only case cited to the contrary, *Duplin v. Whink Products, Co*, 1994 WL 197612 (Conn.Super.Ct., May 2, 1994) is ambiguous in its holding and appears to rule only that a claim of failure to comply with the warning requirements of the FHSA is not preempted.

Furthermore, despite Cotter's efforts to show conflicts, the case law under FIFRA is surprisingly consistent. A long line of cases, including cases from the First, Fourth, Fifth, Seventh, Eighth, Ninth, Tenth, and Eleventh Circuits[9], holds that common law failure to warn claims are preempted by FIFRA.[10] Several of these cases conclude that a common law failure to warn claim is preempted even if the plaintiff alleges that a warning should have been given outside the label.[11] Presumably these

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9. *See, e.g., King v. E.I. Dupont De Nemours & Co.*, 996 F.2d 1346, 1349-50 (CA1) *cert. dismissed*, 510 U.S. 985 (1993); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 748 (CA4 1993); *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1024-25 (CA5 1994); *Shaw v. Dow Brands, Inc.*. 994 F.2d 364, 369-71 & n.4 (CA7 1993); *Bice v. Leslie's Poolmart, Inc.*, 39 F.3d 887, 888 (CA8 1994); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 561 (CA9 1995); *Arkansas-Platte & Gulf Parntership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1179 (CA10), *cert. denied*, 510 U.S. 813 (1993); *Papas v. Upjohn*, 985 F.2d 516, 518-19 (CA11) *cert. denied*, 510 U.S. 913 (1993).

10. The only case to the contrary, *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1542 (CA D.C.), *cert. denied*, 469 U.S. 1062 (1984) was based on a ruling that common law damage claims do not impose any requirements on the manufacturer and therefore are not preempted. That decision may no longer be good law in light of this Court's decision in *Cipollone*, but regardless, its holding has nothing to do with this case.

11. *See Papas v. Upjohn*, 985 F.2d at 519; *Worm v. American Cyanamid Co.*, 5 F.3d at 748; *Taylor AG Indus. v. Pure-Gro*, 54 F.3d at 561; *Goodwin v. Bacon*, 127 Wash.2d 50, 896 P.2d 673, 681 (Wash. 1995); *Jenkins v. Amchem Prods., Inc.*. 256 Kan. 602, 886 P.2d 869, 881-81

cases rely on the generally accepted recognition that the common law duty to warn "is nothing more than a duty to label a product to provide information." *Arkansas-Platte & Gulf v. Van Waters & Rogers* 981 F.2d 1177, 1179, (CA10) *cert. denied* (1993) 519 U.S. 813. *See also King v. E.I. Du Pont De Nemours & Co.*, 806 F.Supp. 1030, 1037, n.4 (D.Me. 1992), *aff'd* 996 F.2d 1346 (CA1 1993) ("We can see no more effective way to warn potential users of the dangers of a product than by product labels.")

A separate and distinct line of cases under FIFRA and similar federal laws concerns state statutes that impose non-label warning requirements without regard to the contents of the product label. Again, the decisions are uniform, all declining to find preemption. Thus, in *New York State Pesticide Coalition, Inc. v. Jorling*, 874 F.2d 115, 116-17 (CA2 1989), the court held that state requirements concerning warnings to the general public on signs, posted notices and newspaper advertisements did not constitute labeling under FIFRA and were not preempted. As noted by the court, FIFRA was intended to set standards for pesticide labeling, "not to prevent states from regulating the 'sale and use' of the poisonous chemical substances through mandatory written, printed or graphic materials revealing the ingredients." (*Id.* at 119.)

The *Jorling* decision is consistent with cases interpreting analogous preemption provisions in other federal laws as well. These cases similarly have held that preemption of "labeling" requirements does not apply to statutes that regulate information provided in non-label channels of communication such as posted notices, advertising, menus, etc. *See National Broiler Council v. Voss*, 44 F.3d 740, 748-49 (9th Cir. 1994) (portion of state

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(Kan. 1994) *cert. denied*, 116 S.Ct. 80 (1995).

law prohibiting advertising of poultry products as fresh, not preempted by federal Poultry Products Inspection Act, 21 U.S.C. § 467e, which precludes state labeling requirements); *Grocery Mfrs. of America v. Gerace*, 755 F.2d 993, 996, 1002-03, 1006 (CA2 1985) *cert. denied* 474 U.S. 820 (1985) (New York law regarding information on signs, menus and serving containers was not preempted by federal Food, Drugs and Cosmetics Act, Meat Inspection Act and Poultry Products Inspection Act, even though package labeling requirements were preempted); *American Meat Institute v. Ball*, 424 F.Supp. 758, 763, 766 (W.D. Mich. 1976) (notices required by state law to be posted in restaurants are not labels and not preempted by federal Wholesome Meat Act, 21 U.S.C. § 678, prohibiting state "labeling requirements").

Thus, the case law divides along obvious and distinct lines. Where common law failure to warn claims are at issue, the FIFRA cases are nearly uniform in holding that such claims are preempted. In contrast, where a state statute requires information to be communicated in non-label channels, the case law is equally consistent in hold that the state requirement is not preempted. The Ninth Circuit's decision in *Allenby* falls comfortably into the latter line of cases as does the decision of the Court of Appeal in *Cotter*.

C. The Court of Appeal's Reasoning that FIFRA and FHSA Preemption are not Absolutely Identical is Correct and is Consistent with the Decisions of This and Other Courts

The substantive decision of the Court of Appeal is both correct and consistent with the case law under the FHSA, FIFRA and related statutes. The Court of Appeal's reasoning is equally unassailable. It recognized, as have

many courts,[12] that the preemption provisions in FIFRA and the FHSA are "essentially identical." *Cotter*, 53 Cal.App.4th at 1390, n.16. The *Cotter* Court, however, noted significant differences as well: First, that FIFRA defines "labeling" to include all written material accompanying the pesticide at any time, 7 U.S.C. § 136(p)(2), whereas the FHSA limits the definition to accompanying literature that contains directions for use, 15 U.S.C. § 1261(n); and second, that the EPA approves the actual label under FIFRA, whereas, under the FHSA, the Consumer Product Safety Commission does not.[13] These differences have been noted by other courts as well. *See Jenkins v. James B. Day & Co.*, 634 N.E.2d at 1004 n.4

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12. *See Busch v. Graphic Color Corp.*, 662 N.E.2d at 405 (FIFRA provision is "substantively equivalent" to the FHSA's preemption provision.); *Moss*, 985 F.2d at 740 n.3 ("The preemption language of the two statutes is nearly identical."); *Comeaux*, 81 F.3d at 43-44 (referring to "almost identical preemptive provisions" of FIFRA and FHSA).

13. EPA's extensive oversight of pesticide labels under FIFRA has frequently been cited as a basis for preemption. *See, e.g., Papas*, 985 F.2d at 519 ("If a pesticide manufacturer places EPA-approved warnings on the label and packaging of its product, its duty to warn is satisfied and the adequate warning issue ends."); *Worm*, 5 F.3d at 747 ("Given the comprehensive nature of the FIFRA labeling process, it is apparent that [FIFRA's preemption provision] dictates preemption of any state common law cause of action that rests on an alleged failure to warn or communicate information about a product through its labeling."); *Taylor AG*, 54 F.3d at 560 (discussing rigorous label approval process under FIFRA); *King*, 806 F.Supp. at 1036 (because labels were approved by the EPA under FIFRA, failure to warn claim is preempted).)

("Our analysis could be different if we were considering whether a plaintiff's inadequate labeling claim is preempted by FIFRA, rather than by the FHSA").

The Court of Appeal's refusal to blindly apply FIFRA preemption analysis to the FHSA is absolutely consistent with this Court's numerous rulings that congressional intent is the touchstone of preemption analysis and is to be discerned from the language of the statute, the statutory framework and the structure and purpose of the statute as a whole. *See Medtronic*, 116 S.Ct. at 2250-51 (citing *Cipollone*, 505 U.S. at 516; 112 S.Ct. at 2617; *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 96, 111, 112, 112 S.Ct. at 2381-2382, 2383, 2390; *Malone v. White Motor Corp.*, 435 U.S. 479, 504, 98 S.Ct. 1185, 1190, 55 L.Ed.2d 443 (1978).) FIFRA and the FHSA are different statutes, enacted by different congresses in different time periods, with different regulatory schemes. It would be improper for any court simply to superimpose a preemption analysis under one statute on the other.

Finally, the Court of Appeal's analysis that FIFRA and FHSA preemption are not absolutely identical is not dispositive of this case. Even under FIFRA, the courts have concluded that Proposition 65 point-of-sale signs are not preempted. *Allenby*, 958 F.2d at 947. Thus, the "conflict presented by Cotter has no bearing on the outcome of the case and does not merit review by this Court.

D. The Court of Appeal's Distinction Between Common Law Failure to Warn Claims and Proposition 65 is Correct and Does Not Conflict with This Court's Decisions

Cotter argues that the Court of Appeal's distinction between preemption of common law failure to warn claims and state statutory non-label warning requirements conflicts with the decisions of this Court holding that the term "requirements," for purposes of preemption analysis, applies equally to requirements imposed through common law and through state statutes. Petition at 15. The meaning of the term "requirements," however, was never presented in this case. All parties have always acknowledged that Proposition 65 is a "requirement" for purposes of preemption analysis. The only issue is whether it is a "**labeling**" requirement. Thus, the rulings by this Court that common law claims and statutory enactments are encompassed in the term "requirements" do not apply.

Finally, Cotter argues that the Court of Appeal mistakenly applied the standards for facial preemption to an as-applied challenge to Proposition 65. Petition at 15. In fact, however, as presented by Cotter and framed by the Court of Appeal, the issue presented was a classic facial challenge to the statute: "Does the FHSA preempt Proposition 65 warnings because point of sale signs are labels as defined by the FHSA?" *Cotter*, 53 Cal.App.4th at 1379.[14/] The standard applied by the Court of Appeal was therefore correct and does not conflict with the decisions of this or any other court.

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14. As noted previously, note 3 *supra*, Cotter did raise an as-applied challenge to Proposition 65. That issue is not, however, before this Court.

CONCLUSION

For the second time, this Court has been presented with the same narrow question of the definition of cautionary labeling requirements under the FHSA, and its application to Proposition 65. The ruling of the California Court of Appeal is correct and consistent with all of the relevant case law, as were the earlier rulings of the federal courts. The petition for writ of certiorari should be denied.

Respectfully submitted,

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or graphic matter upon the immediate container of any substance or, in the case of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (1) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (2) on all accompanying literature where there are directions for use, written or otherwise." (15 U.S.C. § 1261(n).)

DISCUSSION

Cotter raises two issues on appeal: (1) Does the FHSA preempt Proposition 65 warnings because point of sale signs are labels as defined by the FHSA? (2) If point of sale signs are not labels, does the FHSA still preempt Proposition 65 because the state statute imposes a de facto labeling requirement? We address each of these issues separately.

I. *Point of Sale Signs Are Not Labels Under the FHSA*

(1a) Cotter contends the court erred in denying its summary judgment motion because Proposition 65 imposes a "cautionary labeling requirement" which is preempted by the FHSA. Since Cotter presents a facial challenge to Proposition 65, it must establish Proposition 65 would not be valid under any set of circumstances. (*Chemical Specialties Mfrs. Ass'n, Inc.* v. *Allenby* (9th Cir. 1992) 958 F.2d 941, 943, cert. den. (1992) 506 U.S. 825 [113 S.Ct. 80, 121 L.Ed.2d 44] (*Allenby*).) Thus, to find preemption, we " 'must determine that *all* possible consumer product warnings that would satisfy Proposition 65 conflict with provisions' " of the FHSA. (*Comm. of Dental Amalgam Mfrs. & Distribs.* v. *Stratton* (9th Cir. 1996) 92 F.3d 807, 810 (*Stratton*).)

The People claim Cotter could satisfy Proposition 65 by using point of sale signs. This method, they assert, does not conflict with the preemption provision of the FHSA. They rely on *Allenby*, *supra*, 958 F.2d 941, which held such signs are not labels under the FHSA. Cotter, however, claims the Ninth Circuit in *Allenby* misapplied and misinterpreted federal and state law and the trial court erred by following *Allenby*.

In deciding whether *Allenby* represents good law, we first review the federal preemption doctrine and examine the most recent United States

Supreme Court decisions. We then explain why *Allenby* correctly found point of sale signs are not labels under the FHSA.

A. *Standard of Review*

The trial court denied Cotter's motion for summary judgment based on preemption and granted the People's motion for summary adjudication to Cotter's defense of preemption. Summary adjudication was proper only if the defense of preemption presented no triable issue of material fact and Cotter could not raise the defense as a matter of law. (Code Civ. Proc., § 437c, subd. (f)(1).) Since the parties do not dispute the facts related to preemption and the summary adjudication raises a purely legal question, we employ de novo review. (*Schrader* v. *Scott* (1992) 8 Cal.App.4th 1679, 1684 [11 Cal.Rptr.2d 433].)

B. *Preemption Doctrine*

(2) "Preemption analysis starts with the presumption that the traditional police powers of states are not displaced by federal law unless displacement was the 'clear and manifest purpose of Congress.' " (*Allenby, supra*, 958 F.2d 941, 943; accord with *Medtronic, Inc.* v. *Lohr* (1996) __ U.S. __, __ [116 S.Ct. 2240, 2248, 135 L.Ed.2d 700] (*Medtronic*).)[6] One reason for this presumption is Congress has the power to make its intention clear. "[I]f the court erroneously finds preemption, the State can do nothing about it, while if the court errs in the other direction, Congress can correct the problem." (958 F.2d at p. 943.)

The second presumption underlying a preemption analysis requires a determination of Congress's purpose, which " 'is the ultimate touchstone' in every pre-emption case. [Citations.]" (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2250].) We determine intent primarily "from the language of the pre-emption statute and the 'statutory framework' surrounding it. [Citation.]" (*Id.* at p. __ [116 S.Ct. at p. 2251].) "Also relevant, however, is the 'structure and purpose of the statute as a whole,' [citation], as revealed not only in the text, but through the reviewing court's reasoned understanding of

[6]Justice Stevens delivered the opinion of the court. Justices Kennedy, Souter, Ginsburg, and Breyer joined with respect to __ U.S. at pages __-__ [116 S.Ct. at pages 2245-2251] (pts. I, II, and III); __ U.S. at pages __-__ [116 S.Ct. at pages 2253-2258] (pt. V); and __ U.S. at page __ [116 S.Ct. at page 2259] (pt. VII). Justices Kennedy, Souter, and Ginsburg joined with respect to __ U.S. at pages __-__ [116 S.Ct. at pages 2251-2253] (pt. IV) and __ U.S. at pages __-__ [116 S.Ct. at pages 2258-2259] (pt. VI). Justice Breyer filed an opinion concurring in part and concurring in the judgment. Justice O'Connor filed an opinion concurring in part and dissenting in part, in which Justices Rehnquist, Scalia, and Thomas joined. All references, unless otherwise specified, refer to Justice Stevens's opinion.

he way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." (*Ibid.*)

(3) If the statute does not have an express preemption clause, state law is only preempted if (1) the law actually conflicts with federal law, or (2) federal law "so thoroughly occupies a legislative field " ' "as to make reasonable the inference that Congress left no room for the States to supplement it." ' [Citation.]" (*Cipollone* v. *Liggett Group, Inc.* (1992) 505 U.S. 504, 516 [112 S.Ct. 2608, 2617, 120 L.Ed.2d 407] (*Cipollone*).) "When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a 'reliable indicium of congressional intent with respect to state authority' [citation], 'there is no need to infer congressional intent to pre-empt state laws from the substantive provisions' of the legislation. [Citation.]" (*Id.* at p. 517 [112 S.Ct. at p. 2618].)

In this case, Congress enacted an express preemption clause and we only need to "identify the domain expressly pre-empted." (See *Cipollone*, *supra*, 505 U.S. 504, 517 [112 S.Ct. 2608, 2618].) Moreover, we must narrowly read the preemption clause because Proposition 65 is an instance of the state exercising its police power. (*Medtronic*, *supra*, __ U.S. __, __ [116 S.Ct. 2240, 2250]; *Ketchum* v. *Hyundai Motor Co.* (1996) 49 Cal.App.4th 1672, 1678 [57 Cal.Rptr.2d 595].)

Cipollone and Medtronic

The two most recent United States Supreme Court cases to consider preemption are *Cipollone*, *supra*, 505 U.S. 504 and *Medtronic*, *supra*, __ U.S. __ [116 S.Ct. 2240]. Both the People and Cotter contend *Cipollone* supports their position. The Supreme Court decided *Medtronic* while this appeal was pending, and both parties discussed its impact on this appeal at oral argument.

In *Cipollone*, the United States Supreme Court found the amended Public Health Cigarette Smoking Act of 1969 (Smoking Act) preempted common law claims based on a failure to warn about the hazards of smoking, but not those premised on express warranty, intentional fraud and misrepresentation, or conspiracy. (505 U.S. 504 [112 S.Ct. 2608].) The federal statute set forth the exact warning to be placed on each package[7] and the preemption clause specified " '[n]o requirement or prohibition based on smoking and health

[7] The Smoking Act required the following warning: " 'WARNING: THE SURGEON GENERAL HAS DETERMINED THAT CIGARETTE SMOKING IS DANGEROUS TO YOUR HEALTH.' " (*Cipollone*, *supra*, 505 U.S. at p. 508 [112 S.Ct. at p. 2613].)

shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.' " (*Id.* at p. 515 [112 S.Ct. at p. 2617].)

When determining whether federal law expressly preempted the common law claims, the court in *Cipollone*, held the following as the central inquiry: "[W]e ask whether the legal duty that is the predicate of the common-law damages action constitutes a 'requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion,' giving that clause a fair but narrow reading." (505 U.S. 504, 524 [112 S.Ct. 2608, 2621].) Thus, federal law preempted state claims based on inadequate warnings about health risks.

The United States Supreme Court further refined preemption analysis in *Medtronic, supra*, __ U.S. __ [116 S.Ct. 2240]. In *Medtronic*, the manufacturer of a pacemaker argued the Medical Device Amendments of 1976 (MDA) to the federal Food, Drug and Cosmetics Act governed the requirements for medical devices and its preemption clause prevented the plaintiff's claims of negligence and strict liability based on a defective device and inadequate warnings. (*Id.* at p. __ [116 S.Ct. at p. 2250].) The preemption provision under the MDA provided: "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement— [¶] (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and [¶] (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." (21 U.S.C. § 360k(a).)

The court in *Medtronic* stated courts should broadly interpret the preemption provision of federal statutes with limited applicability and narrowly interpret those statutes with general applicability. Accordingly, the court in *Cipollone* broadly interpreted the word "requirement" in the preemption provision because: "The pre-emptive statute in *Cipollone* was targeted at a limited set of state requirements—those 'based on smoking and health'—and then only at a limited subset of the possible applications of those requirements—those involving the 'advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of' the federal statute. [Citation.]" (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2252], fn. omitted.)

In contrast to the Smoking Act, the MDA in *Medtronic* applied to all medical devices, warranting a narrow interpretation of "requirement." The

court defined "requirement" under the MDA to include only those situations in which the state and federal government had imposed a conflicting "duty" on the manufacturer. (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2251].) The FDA approved the marketing of the pacemaker in *Medtronic* because it was " 'substantially equivalent' to devices already on the market," and had not specifically evaluated the pacemaker. (*Id.* at p. __ [116 S.Ct. at p. 2248].) Accordingly, the court found the MDA had not issued "any requirement" applicable to this device and it did not preempt the state claim alleging negligent design. (*Id.* at p. __ [116 S.Ct. at p. 2249].)

The court in *Medtronic* also held the MDA did not preempt claims based on inadequate labeling. The MDA required manufacturers of every medical device to include a label containing " 'information for use, . . . and any relevant hazards, contraindications, side effects, and precautions. [Citation.]" (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2256].) The labeling requirements did not apply specifically to the pacemaker; therefore, the court found the federal government had not imposed a labeling "requirement" for the pacemaker.

The court explained why a decision regarding preemption should consider the "generality" of the federal statute: "The generality of those requirements make [*sic*] this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2258].) Instead, ". . . the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." (*Ibid.*)

When both the state and federal requirements reflect "generic concerns" rather than specific regulations, they probably will not conflict, resulting in no preemption. (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2258].) Preemption occurs "only where a particular state requirement threatens to interfere with a specific federal interest." (*Id.* at p. __ [116 S.Ct. at p. 2257].)

D. *The FHSA, Proposition 65, and Preemption*

(1b) Only one case, *Allenby, supra*, 958 F.2d 941, has reviewed preemption under the FHSA and Proposition 65. It held the FHSA did not preempt Proposition 65.[8]

Cotter argues *Allenby* does not represent good law because it conflicts with the holding in *Cipollone*, contradicts other state and federal decisions made post-*Cipollone*, and ignored and failed to defer to the conclusions of the Consumer Product Safety Commission (CPSC). To support its contention, Cotter cites one other Proposition 65 case in the district court (*Committee of Dental Amalgam Alloy Mfrs.* v. *Henry* (S.D.Cal. 1994) 871 F.Supp. 1278), which was recently reversed in *Stratton, supra*, 92 F.3d 807, and tort claims preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Prior to assessing each of Cotter's criticisms of *Allenby*, we briefly summarize *Allenby*'s analysis of preemption under the FHSA and conduct our own independent analysis of preemption and the FHSA.

1. *Allenby*

When analyzing preemption under the FHSA, the court in *Allenby, supra*, 958 F.2d 941, 946, noted the preemption provision in the FHSA only applies to "cautionary labeling" on packages (15 U.S.C. § 1261 note). The Act defines labels as including accompanying literature only if the material contains "directions for use." (15 U.S.C. § 1261(n).) Thus, if point of sale signs were not "directions for use," they represented a method in which a manufacturer could satisfy Proposition 65 without requiring warning labels in addition to the FHSA.

The court rejected the argument that Proposition 65 warnings "impliedly" direct the consumer to handle the product to "avoid or minimize direct exposure" and were therefore directions for use. (*Allenby, supra*, 958 F.2d 941, 949.) The court explained this was a "nonsensical reading" of the term "directions for use" and it agreed with the lower court's comments during oral argument about a sign stating, " 'this product may cause birth defects.' " The Ninth Circuit quoted the lower court as responding: " '[D]oesn't tell you whether it's going to cause defects if you pour it on your feet, or if you drink it, or if you poke it in your ear, it just says that it may cause birth defects. How is that a direction for use?' " (*Ibid.*) Instead, the court in *Allenby*

[8]*Allenby* also found Proposition 65 was not preempted by the Federal Insecticide, Fungicide, and Rodenticide Act.

determined Congress's intent more likely related to "how much of a deterrent to use, or how long a paint solvent should be mixed."[9] (*Ibid.*)

The court in *Allenby* concluded Proposition 65 did not frustrate any congressional purpose. The FHSA regulates cautionary labeling to promote uniformity but permits the states through the use of point of sale signs to regulate the sale and use of hazardous chemicals. (*Allenby, supra*, 958 F.2d 941, 950.)

2. *Allenby's analysis of labels under the FHSA remains good law post-Cipollone*

(i) *Predicate duty analysis does not apply to general statutes*

3

(4) Cotter argues *Allenby* is not good law because *Cipollone, supra* 505 U.S. 504, 524 [112 S.Ct. 2608, 2621], held the central inquiry for preemption is whether the state and federal statutes have the same predicate duty. Cotter contends Proposition 65 and the FHSA have the same "predicate duty": the legal duty to warn of toxic dangers.

Cotter, however, does not consider the recent decision of *Medtronic*, which explained the predicate duty analysis does not apply when the federal statute merely requires a general duty to inform users and purchasers of potentially dangerous items. (__ U.S. __, __ [116 S.Ct. 2240, 2258].) When the predicate for the plaintiff's claims is the general duty to inform users and purchasers of potentially dangerous items and the federal government has not implemented or enforced specific federal requirements, general obligations imposed by the state do not threaten the federal requirements. (*Ibid.*)

Indeed a recent Ninth Circuit opinion, relying on the analysis of *Medtronic*, held the MDA does not preempt Proposition 65 warnings[10] for

Allenby also found no preemption because the warnings required under Proposition 65 were not "necessarily nonidentical" to the requirements under the FHSA. (958 F.2d at p. 950.) Since neither statute required specific language, a manufacturer could *choose* to use a label which satisfied both Proposition 65 and the FHSA. However, after *Cipollone*, once Congress has enacted a preemption amendment, the issue is not whether the warnings can never be the same, but whether the warnings are identical. The requirements under Proposition 65 are clearly not identical to the warnings under the FHSA. Thus, we disagree with the holding in *Allenby* to the extent it found no preemption on this basis.

[10] Proposition 65 imposed consumer warning requirements for dental amalgam because it contained dental mercury.

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dental amalgam.[11] (*Stratton, supra*, 92 F.3d 807, 810.) "Proposition 65 is a state law of general applicability which was *not* enacted 'with respect to' medical devices." (*Id.* at p. 813.) Rather, "Proposition 65 applies to *all* products and services that pose a health risk to the public." (*Ibid.*) The court concluded: "Thus, we hold that the consumer warning requirement under California's Proposition 65 is not 'specific' enough to trigger preemption because it is 'not the kind[] of requirement[] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements.' " (*Ibid.*)

Following both *Medtronic* and *Stratton*, the "predicate duty" analysis for preemption does not apply when both the federal and state statutes require a general warning for a variety of products and do not target specific products. As noted above, Proposition 65 is a general statute which applies to all products and services posing a health risk. Similarly, the FHSA is a general statute which requires warnings on labels for substances it determines are hazardous. (15 U.S.C. § 1261.) A " 'hazardous substance' " includes: "Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." (15 U.S.C. § 1261(f)(1)(A).)

Given the generality of Proposition 65 and the FHSA, Cotter's criticism of *Allenby* for failing to consider the statutes' predicate duty has no merit. Unlike the Smoking Act in *Cipollone*, which provided requirements for a particular product and specified the exact wording for the warning, the requirements of the FHSA apply to a variety of products in numerous industries. In this situation an analysis of the predicate duty becomes meaningless.

(ii) *Allenby correctly found point of sale signs are not labels*

Allenby's analysis of labels under the FHSA does not contradict the reasoning in either *Cipollone* or *Medtronic*.[12] Our independent examination of Proposition 65 and the FHSA confirms *Allenby*'s finding on point of sale signs and the FHSA.

[11]The two component parts of dental amalgam—dental mercury and amalgam alloy—are separately regulated by the MDA; therefore, the court concluded the MDA covered dental amalgam. (*Stratton, supra*, 92 F.3d 807, 810.)

[12]We express no opinion about *Allenby*'s finding that FIFRA did not preempt Proposition 65 warnings.

(1c) As with any state law regulating health and safety, we begin by presuming Proposition 65 is not displaced. (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2248].) Since the FHSA does have a specific preemption clause, we need to determine "the domain expressly pre-empted." (*Cipollone, supra*, 505 U.S. 504, 517 [112 S.Ct. 2608, 2618].) We determine this "domain" by examining the language of the preemption statute, its " 'statutory framework,' " and the "structure and purpose of the statute as a whole" (*Medtronic, supra*, __ U.S. at p. __ [116 S.Ct. at p. 2251]).

As already stressed, Congress enacted an explicit preemption provision in the FHSA prohibiting a state to establish a cautionary labeling requirement for hazardous substances covered by the FHSA "unless such cautionary labeling requirement is identical to the labeling requirement" in this act. (15 U.S.C. § 1261 note.) The act defines label as a "display of written, printed, or graphic matter upon the immediate container of any substance . . . and (2) on all accompanying literature where there are directions for use, written or otherwise." (15 U.S.C. § 1261(n).)

Congress chose to restrict the definition of a label to include accompanying literature only when that material contains "directions for use." (15 U.S.C. § 1261(n).) These words indicate the warning must tell the user how to use the product. This situation resembles the one in *Medtronic*, where the court refused to interpret "requirement" in the preemption provision of the MDA to mean "remedy" because ". . . if Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it." (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2251-2252].) Similarly, if Congress wanted preemption under the FHSA to apply to all accompanying literature with "implied" directions for use, as Cotter argues, Congress could have specified that.

In addition to examining the language of the FHSA, we must consider Congress's stated purpose. The FHSA itself does not contain a section setting forth its purpose but Congress enacted the FHSA in 1960 to " 'provide nationally uniform requirements for adequate cautionary labeling of packages of hazardous substances which are sold in interstate commerce and are intended or suitable for household use.' " (*Moss* v. *Parks Corp.* (4th Cir. 1993) 985 F.2d 736, 739, citing House Com. on Interstate and Foreign Commerce, Federal Hazardous Substances Labeling Act, H.R.Rep. No. 1861, 86th Cong., 2d Sess., p. 2 (1960), reprinted in 1960 U.S. Code Cong. & Admin. News, No. 2, p. 2833.) When Congress amended the FHSA in 1966, the legislative history discussed the impracticality of having the states produce potentially 50 different labels for a particular hazardous substance. (*Jenkins* v. *James B. Day & Co.* (1994) 69 Ohio St.3d 541, 545 [634 N.E.2d 998, 1001-1002].)

To assess Congress's purpose we must also consider the structure and framework of the FHSA. Following *Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2250], we must interpret the words in the preemption statute narrowly when the federal statute and state statute have general applicability.

As already stressed, the FHSA is an extremely broad statute. It applies to numerous products in a variety of industries and it does not require specific language on the labels but "merely requires (1) that labels contain the signal word 'WARNING' or 'CAUTION' and (2) words which describe the potential hazard." (*Allenby, supra*, 958 F.2d 941, 950.) Furthermore, the generality of these requirements makes it clear the federal government has not "weighed the competing interests relevant" to the particular hazardous material and has not "reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers" (*Medtronic, supra*, __ U.S. __, __ [1116 S.Ct. 2240, 2258]).

Given the FHSA's general applicability, point of sale signs are unlikely to interfere with the federal government's objectives. Point of sale signs obviously do not require manufacturers to develop more than one label for all 50 states. Moreover, point of sale signs allow the state to regulate sales, a distinctively state interest, without imposing additional labeling requirements on packages. Rather than conflicting with the federal government's objectives, they serve to further the purpose of the FHSA by providing a larger audience with information.

Interpreting Proposition 65's warnings as "implied" direction for use to the consumer to take "steps" to "reduce exposure," as Cotter argues, would create an extensive preemption provision under the FHSA. With such a definition, purely informational signs could be considered implied directions for use. For example, signs merely rating material on the product's appropriateness for minors or adults would constitute labeling. Indeed, price tags could be found to be implied directions for use as one should use expensive items sparingly.

We, therefore, conclude *Allenby* correctly found the FHSA does not preempt Proposition 65 point of sale signs.[13]

[13]The People also argue the FHSA does not preempt Proposition 65 because the state and federal statute warn against different risks. The People contend Proposition 65 addresses harm to the developing fetus (Cal. Code Regs., tit. 22, § 12601, subd. (b)), while the FHSA relates to the risks of chemical pneumonitis, pneumonia, and pulmonary edema caused by aspiration into the lungs and systemic injury from inhaling the vapor. This argument has no merit

3. *Distinguishing FIFRA cases*

To support its argument of preemption, Cotter cites numerous FIFRA cases which found FIFRA preempted common law claims based on inadequate point of sale warnings.[14] (*Taylor AG Industries* v. *Pure-Gro* (9th Cir. 1995) 54 F.3d 555, 560 (*Taylor AG*); *Louisiana-Pacific Corp.* v. *Koppers Co.* (1995) 32 Cal.App.4th 599 [38 Cal.Rptr.2d 257]; *Papas* v. *Upjohn Co.* (11th Cir. 1993) 985 F.2d 516.) Although the preemption provision in FIFRA is essentially identical to the one in the FHSA,[15] that similarity should not obfuscate the differences between the statutes.

Three material differences distinguish FIFRA cases from this case: (1) FIFRA defines a label more expansively than the FHSA; (2) FIFRA is not simply a labeling statute while the FHSA is; and (3) FIFRA cases are predominantly tort common law cases and this is a Proposition 65 enforcement action.

(i) *Differences between the statutes*

FIFRA broadly defines label as the following: "The term 'labeling' means all labels and all other written, printed, or graphic matter— [¶] (A) accompanying the pesticide or device at any time; or [¶] (B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications . . . ." (7 U.S.C. § 136(p)(2).) Congress designated matter "accompanying" the product as a label without any further qualification. Consequently, FIFRA cases do not help us determine Congress's intent when it limited a label under the FHSA to mean accompanying literature providing "directions for use."

More significantly, when examining the "statutory framework" of FIFRA, the differences between the two federal statutes are magnified. Rather than

because, as Cotter asserts, the FHSA includes reproductive toxicity within the meaning of "toxic" (16 C.F.R. § 1500.3(c)(2)(ii)(C) (1996)).

[14]Cotter points out *Burke* v. *Dow Chemical Co.* (E.D.N.Y. 1992) 797 F.Supp. 1128, 1140] (*Burke*) represents the sole post-*Cipollone* case holding FIFRA does not preempt warnings outside of product labeling. The People contend *Burke* correctly applied the "channels of communication" language contained in *Cipollone*. The court in *Cipollone* stated that even if one channel of communication was preempted, other "channels of communication" were not. (*Cipollone*, *supra*, 505 U.S. 504, 528 [112 S.Ct. 2608, 2623].) The court, however, was referring to obligations outside of advertising or the promotion of cigarettes and the statement does not clarify whether labeling includes point of sale signs. Since we find the preemption question under FIFRA and the FHSA to be different, we do not address *Burke*'s interpretation of the court's use of "channels of communication."

[15]FIFRA's preemption clause provides as follows: "Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." (7 U.S.C. § 136v(b).)

creating a mere labeling statute, Congress in 1972, "transformed it [FIFRA] into a comprehensive regulatory statute governing the use and sale of pesticides." (*Louisiana-Pacific Corp.* v. *Koppers Co.*, *supra*, 32 Cal.App.4th 599, 603.) One of the cases emphasized by Cotter, *Taylor AG*, *supra*, 54 F.3d 555, 560, noted the "rigorous label-approval process under FIFRA." The court explained: "Although FIFRA does not prescribe the exact contents of labels, manufacturers are not free, . . . to create pesticide labels in any manner they choose. Rather, . . . the EPA approves each label only after a careful review of the product data and the draft label." (*Ibid.*)

Given the statutory framework of FIFRA, a broad interpretation of the word "label" under FIFRA is consistent with *Medtronic*. Not only does FIFRA define "label" expansively, but it represents a situation "in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers" (*Medtronic*, *supra*, __ U.S. __, __ [116 S.Ct. 2240, 2258]).

In contrast, as already stressed, the FHSA does not (1) have a label approval process, (2) specify the wording to be used on the label, or (3) regulate the sale or use of the hazardous products covered by the federal statute. Instead, as the People contend, Congress has left the states free to regulate the sale and use of these hazardous products. The FHSA has remained a labeling statute and the scope of its preemption differs significantly from FIFRA.[16] Accordingly, cases interpreting FIFRA have "limited relevance" to determinations of preemption and the FHSA. (See *Jenkins* v. *James B. Day & Co.*, *supra*, 634 N.E.2d 998, 1004, fn. 4.)[17]

(ii) *Differences between tort actions and state enforcement actions*

An additional reason for contending the FIFRA cases cited by Cotter are irrelevant, according to the People, is because they involve tort claims rather than the state's enforcement of a statute. In response, Cotter claims FIFRA

[16]To the extent *Allenby*, *supra*, 958 F.2d 941, 945, held the issue of preemption arising under FIFRA is identical to that under the FHSA, we disagree. We do agree with *Allenby*'s conclusion that the preemption provisions in both statutes are essentially identical.

[17]"Because the FHSA requires no federal agency approval of the precise language which appears on the label of a substance covered by the FHSA, it appears that an inadequate warning claim is more readily preempted for a product covered by FIFRA than would a similar inadequate warning claim be for a product covered by the FHSA. Of course, since this case does not involve FIFRA, we do not resolve this question. We discuss FIFRA merely to explain why cases interpreting that statute may be of limited relevance to the issue in this case." (*Jenkins* v. *James B. Day & Co.*, *supra*, 634 N.E.2d 998, 1004, fn. 4.)

tort cases provide an appropriate method of analysis for federal preemption under the FHSA since the basis for requiring a warning under common law and Proposition 65 is the same. Cotter argues "[w]here the reason is the same, the rule should be the same" (Civ. Code, § 3511), and "[t]he law respects form less than substance" (Civ. Code, § 3528).

As Cotter asserts, enforcement and common law actions pose the same questions and issues in a determination of the "domain expressly preempted." Accordingly, we used *Cipollone* and *Medtronic*, actions in tort, to determine the scope of preemption under the FHSA.

After determining the preempted domain, the analyses of tort and enforcement actions diverge in a materially significant respect. Once the court determines a common law claim falls within the reach of the preemption clause, the analysis ceases. The federal government's interest in promoting interstate commerce always trumps the individual's interests in receiving damages.

Unlike a tort action, an enforcement action requires the court to establish whether any method of compliance with the state statute falls outside the scope of the preemption provision. (See *Stratton*, *supra*, 92 F.3d 807, 810.) If any method is beyond the reach of the preemption provision, the statute remains valid. The federal statute sets the standards for sufficient warnings (barring any tort claims on this basis), but does not necessarily prohibit the state from requiring warnings consistent with the preemption provision that regulate the use and sale of these products.

Both *Allenby*, *supra*, 958 F.2d 941, 948 and *Taylor AG*, *supra*, 54 F.3d 555, 560 acknowledged this distinction when discussing preemption and FIFRA. The Ninth Circuit in *Taylor AG* rejected the argument "that liability should be imposed upon the Manufacturers for failure to warn arising from alleged deficiencies in advertisements, point-of-sale warnings, and other materials distributed in connections with a sale." (54 F.3d at p. 561, fn. omitted.) The court in *Taylor AG* reconciled its holding with the one in *Allenby* by explaining the court in *Allenby* "merely" held "non-label warnings were not preempted by FIFRA," but *Allenby* admitted " '[t]he argument against product liability suits for inadequate labeling is strong.' " (*Taylor AG*, *supra*, at p. 561, fn. 2, quoting *Allenby*, *supra*, at p. 948.)

Cotter claims the two Ninth Circuit cases, *Allenby* and *Taylor AG*, are inconsistent, with the latter representing the better law. However, as both the People and the court in *Taylor AG* point out, the two courts were simply

addressing different types of actions.[18] In finding Proposition 65 is not preempted under the FHSA, because point of sale signs are not labels and do not provide "directions for use," we are not opening the door to common law tort claims premised on the inadequacy of the product label.

Finally, Cotter claims tort actions and enforcement actions are the same because a company must pay a penalty when it violates the statute. The penalty, Cotter claims, has the same consequences as an award for damages. This argument, however, ignores the vital distinction between the two. As the People point out, an enforcement action never requires the court to assess the adequacy of the label, while that is the task facing the court in a tort action. In an enforcement action, the court simply looks to see whether the company has complied with the mandate of the statute.

4. *The CPSC's interpretation of "label" under the FHSA is clearly erroneous*

Cotter contends the court in *Allenby* erred by ignoring the CPSC's conclusion that point of sale signs qualify as a "direction for use." In response to a request from the Chemical Specialties Manufacturers Association for an advisory opinion, Clement D. Earhardt III from the Office of General Counsel of the CPSC concluded on March 6, 1991, the following: "A warning that a product can cause cancer or birth defects is not an express direction for use. Nevertheless, it conveys the information that, in using the product, steps should be taken to minimize or eliminate exposure. Stated another way, the warning itself can also serve as a direction for use." (Advisory Opn. No. 312, p. 3.) The opinion continued: "Therefore, although the warning quoted in your inquiry does not necessarily convey specific actions to be taken in the use of the product, it does convey information about how the product should be used (steps should be taken to reduce exposure). Accordingly, this office views the statement as a direction for use. It follows, therefore, that signs and the like bearing such warnings are 'accompanying literature containing directions for use' and thus are labeling under FHSA § 2(n)."[19] (*Id.* at p. 4.)

The People respond that the defendant in *Allenby* presented this argument and, rather than ignoring it, the court clearly rejected it. Furthermore, the

[18]Dicta in *Taylor AG* suggested the court agreed point of sale signs, even under the broad definition of label in FIFRA, did not constitute labeling. The court stated *Allenby* did not address "whether common law damages could be imposed for the absence of these *non-label* [point of sale signs] warnings." (*Taylor AG, supra*, 54 F.3d 555, 561, fn. 2, italics added.) Thus, it identified point of sale signs as "non-label[s]."

[19]Cotter requests this court to take judicial notice of a letter from CPSC General Counsel Eric A. Rubel dated October 17, 1995, stating Advisory Opinion No. 312 has never been modified, revoked, suspended, or superseded. We grant judicial notice of this letter.

People contend Advisory Opinion No. 312 is not a long-standing administrative application of the statute and is litigation-inspired because it responds to a request during litigation from defense counsel in *Allenby*. Litigation-inspired opinions have no authority (*Bowen* v. *Georgetown University Hospital* (1988) 488 U.S. 204, 212 [109 S.Ct. 468, 473-474, 102 L.Ed.2d 493]), but generally courts have applied this rule only when the administrative agency is a party to the litigation.

The People also claim letters from the general counsel state the March 6, 1991, advisory opinion "did not express a direct opinion on preemption. . . ."[20] Therefore, according to the People, the letter from general counsel is not entitled to deference.

The People's final argument against deferring to the CPSC's advisory opinion is the opinion's interpretation contravenes the language of the statute and regulations. We agree with this assertion and, for the reasons explained fully above, we find the CPSC's interpretation is " 'plainly erroneous' " and entitled to no deference. (*Stinson* v. *U.S.* (1993) 508 U.S. 36 [113 S.Ct. 1913, 1919, 123 L.Ed.2d 598]; *Dix* v. *Superior Court* (1991) 53 Cal.3d 442, 460 [279 Cal.Rptr. 834, 807 P.2d 1063]).

For the foregoing reasons we find point of sale signs pursuant to Proposition 65 do not constitute "directions for use" and are not preempted by the FHSA. We now turn to Cotter's claim of de facto labeling.

II. *Proposition 65 Is Not a De Facto Labeling Statute*

(5) Even if point of sale signs are not labels, Cotter argues Proposition 65 can only be implemented by placing labels on a package; therefore, in practice, it is a labeling statute and preempted by the FHSA. Since the question of de facto labeling raises an issue of law and material fact, we independently review the evidence submitted to determine whether it raises a triable issue of material fact. (*Schrader* v. *Scott*, *supra*, 8 Cal.App.4th 1679, 1684.)

To establish a de facto labeling statute, Cotter must show it can only satisfy the requirements of Proposition 65 by using labels. (*Stratton*, *supra*, 92 F.3d 807, 810 [to find preemption a party must show all possible methods of complying with Proposition 65 conflict with the FHSA].) Cotter cannot

[20]We grant the People's request for judicial notice of letters and other documents from the file of the general counsel of the CPSC. One such letter states "[t]he Commission has not formulated a general view of preemption [of Proposition 65] beyond the express preemption provisions in its various statutes." (Letter dated July 3, 1995, from the general counsel for the CPSC to counsel for Cotter.)

establish de facto labeling merely by demonstrating it is difficult or costly to comply. Rather, it must show using point of sale signs is a "physical impossibility." (See *Allenby, supra*, 958 F.2d 941, 948-949 ["[F]or purposes of preemption analysis," the party arguing preemption must show "a physical impossibility of complying" with both Proposition 65 and the federal statute "before succeeding on a claim that Proposition 65 is preempted on this theory."].)

Cotter cites almost no legal authority to support its contention of de facto labeling, but claims point of sale signs cannot be used because they are ineffective and too expensive to implement. Cotter's evidence of "physical impossibility" amounts to little more than submitting a number of conclusions, declarations, and opinions. Interestingly, Cotter fails to explain why, if point of sale signs are so costly and ineffective in communicating a message, manufacturers continue to use them to advertise their goods.

Cotter first argues the warnings required by Proposition 65 "must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure." (Cal. Code Regs., tit. 22, § 12601, subd. (a).) Point of sale signs, he argues, are less effective than product labels in warning consumers. To support this claim he cites a footnote in *King* v. *E.I. Du Pont De Nemours & Co.* ((D.Me. 1992) 806 F.Supp. 1030, 1037, fn. 4]), which was later affirmed in an opinion minus the footnote in *King* v. *E.I. DuPont De Nemours and Co.* ((1st Cir. 1993) 996 F.2d 1346). The footnote merely stated "[w]e can see no more effective way to warn potential users of the dangers of a product than by product labels." (*King* v. *E.I. Du Pont De Nemours & Co., supra*, 806 F. Supp. at p. 1037, fn. 4.) This statement does not establish the ineffectiveness of point of sale signs.

In addition to failing to demonstrate ineffectiveness, Cotter's argument is seriously flawed because a manufacturer does not have to use the best warning method to comply with Proposition 65. The court in *Ingredient Communication Council, Inc.* v. *Lungren* (1992) 2 Cal.App.4th 1480, 1494 [4 Cal.Rptr.2d 216] (*ICC*) confirmed Proposition 65 does not require a manufacturer to use the " 'best' " or most effective method, but merely demands a "reasonable" method. Both the court in *ICC, supra*, 2 Cal.App.4th 1480, 1486 and the safe harbor language set forth in the California Code of Regulations (tit. 22, § 12601, subd. (b)(1)(B)) approve of point of sale signs as a reasonable method.[21]

[21]Cotter argues any method other than labeling would not meet the "reasonableness" test of *ICC, supra*, 2 Cal.App.4th at page 1494. The "reasonableness" test requires the trial court to

Cotter also claims a manufacturer cannot ensure a retailer will properly post the signs without incurring unacceptable costs to implement the program.[22] In support of this argument, Cotter stated it sent signs to its California members on March 1988 and January 1990. Moreover, in January 1994, it sent signs again[23] and directed the members to place both signs "close to each of your own paint factory's products." Cotter also submitted deposition testimony of several retailers explaining the problems they had complying with the manufacturer's requests for them to post point of sale warnings.

To counter Cotter's argument, AYS identified numerous paint and/or adhesive manufacturers complying with Proposition 65 warning signs. Many of True Value Hardware stores did not follow instructions, the People contend, because Cotter did not adequately explain the proper placement of the signs.[24] The People claim once the retailers received explicit instruction about the appropriate location pursuant to the permanent injunction, the majority of those deposed testified they understood the directions and properly complied.[25]

In their final argument, the People maintain Cotter cannot argue de facto labeling because it did not attempt to follow the mandate in *ICC*. The court in *ICC* stated a manufacturer must adjust the warning system in light of operational experience and new facts when attempting to comply with Proposition 65. (*ICC*, *supra*, 2 Cal.App.4th 1480, 1493.) AYS notified Cotter on December 10, 1992, that its stores were not providing warnings for their products containing toluene and Cotter should have taken appropriate steps to remedy the problem. Cotter, the People claim, can exercise a certain level

examine the warning's efficacy and cost before determining whether the warning satisfies Proposition 65. The "reasonableness" test set forth in *ICC*, however, does not apply to point of sale signs. The court in *ICC* limited the "test" to situations in which the trial court had to determine whether "alternative warning methods"—that is, methods outside of the safe harbor warnings—provided a reasonable warning. (*Ibid.*)

[22]Attorneys for the National Paint and Coatings Association filed an amicus curiae brief on behalf of Cotter's de facto labeling argument. Much of the data on the costs associated with point of sale signs is irrelevant to Cotter's inability to use these signs and outside the record.

[23]AYS, an intervener in this action, claims many of these signs did not comply with Proposition 65.

[24]The People contend the directions did not tell retailers to post the signs in front of or next to the spray paints. For example, directions sent January 27, 1992, merely stated: "Signs # 1 and # 2 enclosed should be displayed close to each of your own Paint factory's products."

[25]Cotter insists some retailers did not comply even after being given proper information, establishing manufacturers cannot compel retailers to follow their orders. Cotter, however, misconstrues its burden of proof. It must show it *cannot* comply and, since most retailers did adhere to Cotter's instructions when given the proper information, compliance seems physically possible. As the People point out, Cotter can use a variety of techniques and incentives to encourage acquiescence among the remainder of the retailers.

of control over the True Value stores because members of the cooperative must agree to observe Cotter's bylaws, policies, and procedures.[26]

We find the trial court did not err in finding "Proposition 65 does not impose a de facto labeling requirement on Cotter & Company." Cotter has not established the physical impossibility of meeting Proposition 65 warning requirements with point of sale signs. Cotter may ultimately choose to use a label which complies with both Proposition 65 and the FHSA; however, choosing to use a label does not negate the viability of point of sale signs.

CONCLUSION

The warning requirements of Proposition 65 may be satisfied by point of sale signs which are not "directions for use" or labels under the FHSA. The FHSA, therefore, does not preempt Proposition 65. Additionally, Cotter has failed to prove it cannot use point of sale signs and has not established it cannot use point of sale signs to satisfy Proposition 65 warning requirements. Accordingly, we affirm.

Kline, P. J., and Haerle, J., concurred.

[26]The People claim Cotter could take additional steps to ensure acquiescence. After an action involving Cotter and improper Proposition 65 warnings for methylene chloride paint strippers, the manufacturer remedied the situation by (1) providing clear directions to the stores for the placement of the signs and (2) requiring each store to return a postcard indicating it had properly posted the warning sign. Cotter followed up with phone calls to those stores not returning the postcard.

CALIFORNIA HEALTH AND SAFETY CODE

"(d) To shift the cost of hazardous waste cleanups more onto offenders and less onto law-abiding taxpayers.

"The people hereby enact the provisions of this initiative in furtherance of these rights."

Sections 6, 7 and 8 of Initiative Measure, Nov. 4, 1986, provide:

"Sec. 6. If any provision of this initiative or the application thereof is held invalid, that invalidity shall not affect other provisions or applications of the initiative which can be given effect without the invalid provision or application, and to this end the provisions of this initiative are severable.

"Sec. 7. To further its purposes this initiative may be amended by statute, passed in each house by a two-thirds vote.

"Sec. 8. This initiative shall take effect on January 1, 1987."

Amendment of this section by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

Law Review Commentaries

California's toxics initiative: Making it work. Note, 39 Hast.L.J. 1195 (1988).

Problems with Prop. 65: Will California's toxics initiative hold water? James Dragna, 10 L.A.Law. 18 (April 1987).

§ 25249.6. Required warning before exposure to chemicals known to cause cancer or reproductive toxicity

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

Amendment of this section by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

Law Review Commentaries

Problems with Prop. 65: Will California's toxics initiative hold water? James Dragna, 10 L.A.Law. 18 (April 1987).

Notes of Decisions

Occupational safety and health plan 2
Preemption 1

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1. Preemption

The Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C.A. § 136v] did not preempt this section to extent that it merely imposed restrictions on pesticide sale or use, without requiring additions to or deletions from pesticide package labels; many warning methods, including point-of-sale signs currently designated "safe harbor" under this section, could satisfy requirements of California without infringing on federal supremacy in area of pesticide labeling. D-Con Co., Inc. v. Allenby, N.D.Cal.1989, 728 F.Supp. 605.

Principles of comity would not counsel against Court of Appeal's exercising jurisdiction over petition for mandamus ordering state Occupational Safety and Health Standards Board to include in state plan warning and enforcement provisions of this chapter, although manufacturers' association had sought federal declaratory and injunctive relief that this chapter was preempted in the workplace by federal Occupational Safety and Health Act (OSHA) [29 U.S.C.A. § 651 et seq.] because federal hazard communication standard requires employers to warn employees of potential exposure to certain hazardous materials in workplace and state act related to same occupational safety and health issue. California Labor Federation, AFL-CIO v. California Occupational Safety and Health Standards Bd. (App. 1 Dist.1990) 271 Cal.Rptr. 310, 221 Cal.App.3d 1547, review denied.

2. Occupational safety and health plan

Court of Appeal had power to entertain mandamus petition by labor and environmental

Notes of Decisions

Contents of list 1

1. Contents of list

List of "chemicals known to the state to cause cancer or reproductive toxicity" which Governor was required to publish pursuant to this section, is to include, at minimum, both known human and known animal carcinogens and reproductive toxins identified by reference in applicable Labor Code § 6382(b)(1) and (d), despite Governor's argument that list was to include only known human carcinogens and reproductive toxins referred to in Labor Code § 6382(b)(1) and (d). AFL-CIO v. Deukmejian (App. 3 Dist.1989) 260 Cal.Rptr. 479, 212 Cal. App.3d 425.

§ 25249.9. Exemptions from discharge prohibition

(a) Section 25249.5 shall not apply to any discharge or release that takes place less than twenty months subsequent to the listing of the chemical in question on the list required to be published under subdivision (a) of Section 25249.8.

(b) Section 25249.5 shall not apply to any discharge or release that meets both of the following criteria:

(1) The discharge or release will not cause any significant amount of the discharged or released chemical to enter any source of drinking water.

(2) The discharge or release is in conformity with all other laws and with every applicable regulation, permit, requirement, and order.

In any action brought to enforce Section 25249.5, the burden of showing that a discharge or release meets the criteria of this subdivision shall be on the defendant.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

§ 25249.10. Exemptions from warning requirement

Section 25249.6 shall not apply to any of the following:

(a) An exposure for which federal law governs warning in a manner that preempts state authority.

(b) An exposure that takes place less than twelve months subsequent to the listing of the chemical in question on the list required to be published under subdivision (a) of Section 25249.8.

(c) An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In

any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.
(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

Notes of Decisions

Naturally occurring substances 1

1. Naturally occurring substances

Regulation exempting certain naturally occurring carcinogens and reproductive toxins did not conflict with consumer protection statute requiring clear and reasonable warning before one may lawfully expose person to chemicals which are known to cause cancer or reproductive toxicity. Nicolle-Wagner v. Deukmejian (App. 2 Dist.1991) 281 Cal.Rptr. 494, 230 Cal.App.3d 652, rehearing denied and modified.

Regulation exempting certain naturally occurring carcinogens and reproductive toxins from statutory requirement that warning be given before exposing person to chemicals which are known to cause cancer or reproductive toxicity reasonably effectuated statutory purpose of safeguarding effectiveness of warnings given and removing from regulatory scrutiny those substances which pose only insignificant risk of cancer or birth defects. Nicolle-Wagner v. Deukmejian (App. 2 Dist.1991) 281 Cal.Rptr. 494, 230 Cal.App.3d 652, rehearing denied and modified.

§ 25249.11. Definitions

For purposes of this chapter:

(a) "Person" means an individual, trust, firm, joint stock company, corporation, company, partnership, and association.

(b) "Person in the course of doing business" does not include any person employing fewer than ten employees in his business; any city, county, or district or any department or agency thereof or the state or any department or agency thereof or the federal government or any department or agency thereof; or any entity in its operation of a public water system as defined in Section 4010.1.

(c) "Significant amount" means any detectable amount except an amount which would meet the exemption test in subdivision (c) of Section 25249.10 if an individual were exposed to such an amount in drinking water.

(d) "Source of drinking water" means either a present source of drinking water or water which is identified or designated in a water quality control plan adopted by a regional board as being suitable for domestic or municipal uses.

(e) "Threaten to violate" means to create a condition in which there is a substantial probability that a violation will occur.

(f) "Warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable. In order to minimize the burden on retail sellers of consumer

products including foods, regulations implementing Section 25249.6 shall to the extent practicable place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

Amendment of this section by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

§ 25249.12. Implementation

The Governor shall designate a lead agency and such other agencies as may be required to implement the provisions of this chapter including this section. Each agency so designated may adopt and modify regulations, standards, and permits as necessary to conform with and implement the provisions of this chapter and to further its purposes.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

§ 25249.13. Preservation of existing rights, obligations and penalties

Nothing in this chapter shall alter or diminish any legal obligation otherwise required in common law or by statute or regulation, and nothing in this chapter shall create or enlarge any defense in any action to enforce such legal obligation. Penalties and sanctions imposed under this chapter shall be in addition to any penalties or sanctions otherwise prescribed by law.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

§§ 25249.15 to 25249.18. Rejected

Historical and Statutory Notes

Addition of these sections by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

22 CALIFORNIA CODE OF REGULATIONS
§ 12000 ET SEQ.

(1) For the purposes of this section, a chemical is "naturally occurring" if it is a natural constituent of a food, or if it is present in a food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained; for example, minerals present in the soil solely as a result of natural geologic processes, or toxins produced by the natural growth of fungi.

(2) The "naturally occurring" level of a chemical in a food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data.

(3) A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity. Where a food contains a chemical, in part naturally occurring and in part added as a result of known human activity, "exposure" can only occur as to that portion of the chemical which resulted from such human activity. For purposes of this section, "human activity" does not include sowing, planting, irrigation, or plowing or other mechanical preparation of soil for agricultural purposes; but does include the addition of chemicals to irrigation water applied to soil or crops.

(4) Where a chemical contaminant can occur naturally in a food, the chemical is naturally occurring only to the extent that it was not avoidable by good agricultural or good manufacturing practices. The producer, manufacturer, distributor, or holder of the food shall at all times utilize quality control measures that reduce natural chemical contaminants to the "lowest level currently feasible," as this term is used in the Code of Federal Regulations, Title 21, Section 110.110, subdivision (c) (1988).

(b) A person otherwise responsible for an exposure to a listed chemical in a consumer product, other than food, does not "expose" an individual within the meaning of Section 25249.6, to the extent that the person can show that the chemical was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. Where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, "exposure" can only occur as to that portion of the chemical from other sources.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Section 25249.6, Health and Safety Code.

HISTORY

1. New section refiled 6–19–89 as an emergency; operative 6–22–89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10–20–89. For prior history, see Register 89, No. 10.
2. Emergency Section 12501 repealed 7–10–89; repealer operative 8–9–89. New Section 12501 filed 7–10–89; operative 8–9–89 (Register 89, No. 30).

§ 12502. Exposure to a Listed Chemical in Drinking Water.

(a) A person otherwise responsible for an exposure to a listed chemical which involves the use of drinking water, including the use of drinking water in food or any other consumer product, does not "expose" an individual within the meaning of Section 25249.6 to the extent that the person can show that the listed chemical was contained in drinking water which was received from:

(1) a public water system, as defined in Section 4010.1 of the Health and Safety Code;

(2) a commercial supplier of drinking water; or

(3) a source of drinking water in compliance with all applicable primary drinking water standards for all listed chemicals and the chemical in question is the result of treatment of the water in order to achieve compliance with primary drinking water standards.

Where the source of the listed chemical is in part from such drinking water and in part from other sources, "exposure" can occur only as to that portion of the listed chemical from sources other than such drinking water.

(b) For purposes of subdivision (a), the amount of a listed chemical contained in drinking water shall be determined by sampling of the drinking water at the point of delivery and by testing pursuant to Section 12901. If sampling and testing is impractical, the amount of a listed chemical shall be based on test results of the most recent sample of the drinking water taken by the public water system or the commercial drinking water supplier, provided that all sampling and testing has been conducted at the frequency and in the manner required by law, or alternatively, such amount shall be calculated at five percent of the maximum contaminant level set forth in the primary drinking water standard for the listed chemical.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section filed 7–10–89; operative 8–9–89 (Register 89, No. 30).

§ 12503. Exposure to Water.

A person otherwise responsible for an exposure to a listed chemical does not "expose" an individual within the meaning of Health and Safety Code Section 25249.6 to the extent that the person can show that the listed chemical was contained in water which the person moved or which was handled in the manner described in Section 12401. Nothing in this section shall be interpreted to affect the responsibility for an exposure which arises from any activity other than that described in Section 12401.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section refiled 6–19–89 as an emergency; operative 6–22–89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10–20–89. For prior history, see Register 89, No. 10.
2. Emergency Section 12503 repealed 7–10–89; repealer operative 8–9–89. New Section 12503 filed 7–10–89; operative 8–9–89 (Register 89, No. 30).

§ 12504. Exposure to Air.

A person otherwise responsible for an exposure to a listed chemical in air does not "expose" an individual within the meaning of Health and Safety Code Section 25249.6 to the extent that the person can show that the listed chemical was contained in air that the person received from the ambient air. Where the source of the listed chemical is in part from the ambient air and in part from other sources, "exposure" does not occur as to that portion of the listed chemical from the ambient air to the extent that the person did not put the listed chemical into the ambient air.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Section 25249.6, Health and Safety Code.

HISTORY

1. New section filed 7–10–89; operative 8–9–89 (Register 89, No. 30).

§ 12505. Miscellaneous.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section refiled 6–19–89 as an emergency; operative 6–22–89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10–20–89. For prior history, see Register 89, No. 10.
2. Emergency Section 12505 repealed 7–10–89; repealer operative 8–9–89 (Register 89, No. 30).

Article 6. Clear and Reasonable Warnings

§ 12601. Clear and Reasonable Warnings.

(a) Whenever a clear and reasonable warning is required under section 25249.6 of the Health and Safety Code, the method employed to transmit the warning must be reasonably calculated, considering the alternative

[The next page is 189.]

methods available under the circumstances, to make the warning message available to the individual prior to exposure. The message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm. Nothing in this section shall be construed to preclude a person from providing warnings other than those specified in subdivisions (b), (c), and (d) which satisfy the requirements of this subdivision, or to require that warnings be provided separately to each exposed individual.

(b) Warnings for consumer products exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed to be clear and reasonable. A "consumer products exposure" is an exposure which results from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service.

(1) The warning may be provided by using one or more of the following methods singly or in combination:

(A) A warning that appears on a product's label or other labeling. The term "label" means a display of written, printed or graphic matter upon a product or its immediate container. The term "labeling" means any label or other written, printed or graphic matter affixed to or accompanying a product or its container or wrapper.

(B) Identification of the product at the retail outlet in a manner which provides a warning. Identification may be through shelf labeling, signs, menus, or a combination thereof.

(C) A system of signs, public advertising identifying the system and toll-free information services, or any other system, that provides clear and reasonable warnings.

(D) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

1. Primarily intended for consumption off the premises where sold or distributed:

(i) at least one notice or sign, no smaller than 10 inches wide by 10 inches high, and bearing the warning message set forth in paragraph (4)(E) of this subsection; or

(ii) at least one horizontal strip marker no smaller than 10 1/2 inches wide by 1 1/4 inches high, and bearing the warning message set forth in paragraph (4)(E) of this subsection; or

(iii) a notice no smaller than 5 inches by 5 inches, and bearing the warning message set forth in (4)(E) of this subsection.

(iv) If signs 10 inches high by 10 inches wide are used, the word "warning" shall be centered three-quarters of an inch from the top of the sign in ITC Garamond bold condensed type face all in one-inch capital letters. Three-sixteenths of an inch from the base of the word "warning" shall be a line extending from left to right across the width of the sign one-sixteenth of an inch in thickness. Centered one-half inch below the line shall be the body of the warning message in 36/50 ITC Garamond bold condensed type face with the initial letter of each word, other than the conjunctive "and," capitalized. For the body of the warning message, left and right margins of at least one-half of an inch, and a bottom margin of at least one-half inch shall be observed. Larger signs shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide.

(v) If the 10 1/2 inch by 1 1/4 inch horizontal strip markers are used, the word "WARNING," punctuated by a colon, shall be justified left and located three-sixteenths of an inch from the top of the strip notice in ITC Garamond bold condensed type face all in capital letters measuring eleven sixteenths of an inch in height. Three thirty-seconds of an inch from the base of the word "WARNING" shall be a line extending from left to right across the width of the word "WARNING" and the punctuating colon one thirty-second of an inch in thickness. Located one-fourth of an inch from the top and one-fourth of an inch from the bottom of the strip notice, and to the immediate right of the word "WARNING," shall be the body of the warning message in 12/16 point ITC Garamond bold condensed type face with the initial letter of each word, other than the conjunctive "and," capitalized. The word "WARNING" shall be one-half inch from the left edge of the strip notice and the requisite warning message shall extend to within one-half inch from the right edge.

(vi) If the 5 inch by 5 inch signs are used, they shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide, with both the word "WARNING" and the warning text set in white on a contrasting red background.

(vii) Such sign or notice shall be placed in the retail establishment so as to assure that it is readable and likely to be read either at each retail point of sale or each point of display. Such sign or notice shall be placed either at all retail points of sale or all points of display, but need not be placed at both. If 10 inch by 10 inch signs or notices are placed at the point of display, each shall be placed no more than ten feet from any alcoholic beverage container and in a manner associating the sign or notice with the display. If horizontal strip notices are used, they shall be placed at ten foot intervals horizontally along the display. If a 5 inch by 5 inch sign is used, it shall be conspicuously placed at each retail point of sale (e.g., checkout counter, cash register, cash box) so that it is likely to be read and understood during the sales transaction.

(viii) All measurements specified or referred to in paragraphs (iv), (v) and (vi), above, are not required to be precisely accurate.

2. Provided for consumption on the premises at tables served by food or beverage persons, or sold or distributed through over the counter service:

(i) a notice or sign displayed at each of the tables where alcoholic beverages are served or may be consumed at least 5 inches high by 5 inches wide bearing substantially the same type face and substantially the same proportion of type size and spacing to sign dimension as described in paragraph (D)1. (vi); or

(ii) the warning message set forth in paragraph (4)(E) of this subdivision, placed upon a menu or list in association with the alcoholic beverages listed thereon and served at such premises, or if alcoholic beverages are not listed thereon, on any menu or list provided to patrons in association with the listing of food or beverage offerings, in type size and design, such that the text is conspicuous and likely to be read prior to consumption of alcoholic beverages or,

(iii) at least one 10 inch by 10 inch sign, meeting the specifications set forth in paragraph (D)1. (iv) of this subsection, placed so that it is readable and likely to be read by patrons as they enter each public entrance to the establishment. If the establishment does not have clearly defined physical boundaries delineating those areas where, by permit or license, alcoholic beverages are served, the 10 inch by 10 inch sign shall be posted so that it is readable and likely to be read by patrons as they enter the area or areas where, by permit or license, alcoholic beverages are served; and

(iv) If sold or distributed through over-the-counter service, at least one sign, meeting the specifications set forth in paragraph (D)1. (iv) of this subsection, placed in the retail establishment so that the warning message is, prior to the consumption of alcoholic beverages, readable and likely to be read from all counter locations available to the public. Therefore, a retail establishment providing a warning pursuant to the preceding sentence, also would be required to provide a warning in accordance with either paragraph 2.(i), 2.(ii) or 2.(iii) of this subsection.

3. For premises which are specially licensed to sell and serve alcoholic beverages both on and off the licensed premises (e.g., in facilities that offer both "tasting" and retail sales), the off-sale portion of the premises shall comply with the provisions of subsection (D)1, above, and the portion of the premises where alcoholic beverages are served shall comply with the provisions of subsection (D)2, above.

4. For alcoholic beverages sold or distributed to consumers through the mail or package delivery services, warnings may be provided by incorporating or placing the warning message set forth in paragraph (4)(E) on or in the shipping container or delivery package in such a manner so that the warning message is likely to be read by the recipient prior to consumption of the alcoholic beverage(s).

3. All signs or notices referred to in subsections (D)1., (D)2. and (D)3., above, shall be displayed so that they are clearly visible under all lighting conditions normally encountered during business hours.

(2) To the extent practicable, warning materials such as signs, notices, menu stickers, or labels shall be provided by the manufacturer, producer, or packager of the consumer product, rather than by the retail seller. For alcoholic beverages, the placement and maintenance of the warning shall be the responsibility of the manufacturer or its distributor at no cost to the retailer, and any consequences for failure to do the same shall rest solely with the manufacturer or its distributor, provided that the retailer does not remove, deface, or obscure the requisite signs or notices, or obstruct, interfere with, or otherwise frustrate the manufacturer's reasonable efforts to post, maintain, or periodically replace said materials. For prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining a patient's informed consent shall be deemed to be a clear and reasonable warning.

(3) The warnings provided pursuant to paragraphs (1)(A) and (1)(B) shall be prominently placed upon a product's label or other labeling or displayed at the retail outlet with such conspicuousness, as compared with other words, statements, designs, or devices in the label, labeling or display as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use.

(4) The warning message must include the following language:

(A) For consumer products that contain a chemical known to the state to cause cancer:

"WARNING: This product contains a chemical known to the State of California to cause cancer."

(B) For consumer products that contain a chemical known to the state to cause reproductive toxicity:

"WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

(C) For food, other than alcoholic beverages, sold, served, or otherwise provided in food facilities, as defined in Health and Safety Code section 27521(a), which is intended for immediate consumption:

"WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here."

(D) For fresh fruits, nuts and vegetables:

"WARNING: This product may contain a chemical known to the State of California to cause cancer, or birth defects or other reproductive harm."

(E) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

"WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine and Other Alcoholic Beverages May Increase Cancer Risk, and, During Pregnancy, Can Cause Birth Defects."

(5) A person in the course of doing business, who manufactures, produces, assembles, processes, handles, distributes, stores, sells or otherwise transfers a consumer product which he or she knows to contain a chemical known to the state to cause cancer or reproductive toxicity in an amount which requires a warning shall provide a warning to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning.

(c) Warnings for occupational exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "occupational exposure" is an exposure, in the workplace of the employer causing the exposure, to any employee.

(1) The method employed to transmit the warning must include one of the following alternative methods:

(A) A warning that appears on the label or labeling of a product or substance present or used in the workplace. The label or labeling shall be prominently displayed on the product or substance and the product or substance shall be used under circumstances which make it likely that the warnings will be read and understood by employees or other individuals prior to the exposure for which the warning is given.

(B) A warning that appears on a sign in the workplace posted in a conspicuous place and under conditions that make it likely to be read and understood by employees and other individuals prior to the exposure for which the warning is given.

(C) A warning to the exposed employee about the chemical in question which fully complies with all information, training and labeling requirements of the federal Hazard Communication Standard (29 CFR section 1910.1200, as amended and filed September 30, 1986), the California Hazard Communication Standard (Cal. Code Regs., title 8, section 5194, as amended and filed May 26, 1987), or, for pesticides, the Pesticides and Worker Safety requirements (Cal. Code Regs., title 3, ch. 6, subch. 3, group 3, section 6700 et seq., in effect on February 16, 1988) authorized in Food and Agricultural Code section 12981 (as amended by Statutes of 1980, ch. 926, p. 2945, section 1).

(2) For purposes of paragraph (1)(A) of this subdivision, the warning shall be provided in terms which would provide a clear warning for a consumer product as specified above.

(3) For purposes of paragraph (1)(B) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

"WARNING: This area contains a chemical known to the State of California to cause cancer."

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

"WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm."

(d) Warnings for environmental exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "environmental exposure" is an exposure which may foreseeably occur as the result of contact with an environmental medium, including, but not limited to, ambient air, indoor air, drinking water, standing water, running water, soil, vegetation, or manmade or natural substances, either through inhalation, ingestion, skin contact or otherwise. Environmental exposures include all exposures which are not consumer products exposures, or occupational exposures.

(1) The method employed to transmit the warning must include the most appropriate of the following alternative methods under the circumstances:

(A) A warning that appears on a sign in the affected area. The term "sign" means a presentation of written, printed or graphic matter. The term "affected area" means the area in which an exposure to a chemical known to the state to cause cancer or reproductive toxicity is at a level that requires a warning. A posting of signs in the manner described in section 6776(e)(1) of title 3 of the California Code of Regulations (as amended and filed August 15, 1986) shall be sufficient for purposes of this paragraph.

(B) A warning which is in a notice mailed or otherwise delivered to each occupant in the affected area. Such notice shall be provided at least once in any three-month period.

(C) A warning provided by public media announcements which target the affected area. Such announcements shall be made at least once in any three-month period.

(2) Environmental exposure warnings shall be provided in a conspicuous manner and under such conditions as to make it likely to be read, seen or heard and understood by an ordinary individual in the course of normal daily activity, and reasonably associated with the location and source of the exposure.

(3) For purposes of paragraph (1)(A) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that

an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

"WARNING: This area contains a chemical known to the State of California to cause cancer."

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

"WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm."

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. Amendment of subsection (b) filed 6-7-89 as an emergency; operative 7-1-89 (Register 89, No. 24). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-30-89. For prior history, see Register 88, No. 53.
2. Certificate of Compliance as to 6-7-89 order transmitted to OAL 10-23-89 and filed 11-22-89 (Register 89, No. 48).
3. Editorial correction of printing error in subsection (c)(1)(C) (Register 91, No. 31).

Article 7. No Significant Risk Levels

§ 12701. General.

(a) The determination of whether a level of exposure to a chemical known to the state to cause cancer poses no significant risk for purpose of Health and Safety Code Section 25249.10(c) shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as known to the state to cause cancer. Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.

(b) A level of exposure to a listed chemical, assuming daily exposure at that level, shall be deemed to pose no significant risk provided that the level is determined:

(1) By means of a quantitative risk assessment that meets the standards described in Section 12703;

(2) By application of Section 12707 (Routes of Exposure); or

(3) By one of the following, as applicable:

(A) If a specific regulatory level has been established for the chemical in question in Section 12705, by application of that level.

(B) If no specific level is established for the chemical in question in Section 12705, by application of Section 12709 (Exposure to Trace Elements) or 12711 (Levels Based on State or Federal Standards) unless otherwise provided.

(c) The chemicals, routes of exposure and conditions of use specifically listed in this article do not include all chemicals, routes of exposure and conditions of use that pose no significant risk. The fact that a chemical, route of exposure or condition of use does not appear in this article does not mean that it poses a significant risk.

(d) This article establishes exposure levels posing no significant risk solely for purposes of Health and Safety Code Section 25249.10(c). Nothing in this article shall be construed to establish exposure or risk levels for other regulatory purposes.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

HISTORY

1. New section filed 3-24-88 as an emergency; operative 3-27-88 (Register 88, No. 11). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-27-88.
2. New section refiled 6-27-88 as an emergency; operative 6-27-88 (Register 88, No. 27). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-25-88.
3. New section refiled 10-17-88 as an emergency; operative 10-25-88 (Register 88, No. 44). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 2-23-89.
4. New section refiled 2-21-89 as an emergency; operative 2-23-89 (Register 89, No. 10). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-23-89.
5. Certificate of Compliance including amendment transmitted to OAL 6-9-89 and filed 7-10-89 (Register 89, No. 30).
6. Amendment of subsection (b)(3)(B) filed 11-16-93; operative 12-16-93 (Register 93, No. 47).

§ 12703. Quantitative Risk Assessment.

(a) A quantitative risk assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which, assuming daily exposure at that level, poses no significant risk. The assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer. In the absence of principles or assumptions scientifically more appropriate, based upon the available data, the following default principles and assumptions shall apply in any such assessment:

(1) Animal bioassay studies for quantitative risk assessment shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, the route of exposure, and the extent of tumor occurrence.

(2) The quality and suitability of available epidemiologic data shall be appraised to determine whether the study is appropriate as the basis of a quantitative risk assessment, considering such factors as the selection of the exposed and reference groups, reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors shall be identified and quantified.

(3) Risk analysis shall be based on the most sensitive study deemed to be of sufficient quality.

(4) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.

(5) The absence of a carcinogenic threshold dose shall be assumed and no-threshold models shall be utilized. A linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term expressing the upper bound of potency shall be utilized. Time-to-tumor models may be appropriate where data are available on the time of appearance of individual tumors, and particularly when survival is poor due to competing toxicity.

(6) Human cancer potency shall be derived from data on human or animal cancer potency. Potency shall be expressed in reciprocal milligrams of chemical per kilogram of bodyweight per day. Interspecies conversion of animal cancer potency to human cancer potency shall be determined by multiplying by a surface area scaling factor equivalent to the ratio of human to animal bodyweight, taken to the one-third power. This is equivalent to a scaling factor of 14 when extrapolating from mouse data, and a scaling factor of 6.5 when extrapolating from rat data.

(7) When available data are of such quality that physiologic, pharmacokinetic and metabolic considerations can be taken into account with confidence, they may be used in the risk assessment for inter-species, inter-dose, and inter-route extrapolations.

(8) When the cancer risk applies to the general population, human body weight of 70 kilograms shall be assumed. When the cancer risk applies to a certain subpopulation, the following assumptions shall be made, as appropriate:

Subpopulation	*Kilograms of Body Weight*
Man (18+ years of age)	70
Woman (18+ years of age)	58
Woman with conceptus	58
Adolescent (11-18 years of age)	40
Child (2-10 years of age)	20
Infant (0-2 years of age)	10

(b) For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound

Register 93, No. 46-48, 11-26-93

7 U.S.C. § 136

class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

(p) Label and labeling

(1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

15 U.S.C. § 1261 ET SEQ.

the above-named dosages or concentrations, the human data shall take precedence.

(i) The term "corrosive" means any substance which in contact with living tissue will cause destruction of tissue by chemical action; but shall not refer to action on inanimate surfaces.

(j) The term "irritant" means any substance not corrosive within the meaning of subparagraph (i) of this section which on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction.

(k) The term "strong sensitizer" means a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Secretary. Before designating any substance as a strong sensitizer, the Secretary, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity.

(*l*)(1) The terms "extremely flammable", "flammable", and "combustible" as applied to any substance, liquid, solid, or the content of a self-pressurized container shall be defined by regulations issued by the Commission.

(2) The test methods found by the Commission to be generally applicable for defining the flammability or combustibility characteristics of any such substance shall also be specified in such regulations.

(3) In establishing definitions and test methods related to flammability and combustibility, the Commission shall consider the existing definitions and test methods of other Federal agencies involved in the regulation of flammable and combustible substances in storage, transportation and use; and to the extent possible, shall establish compatible definitions and test methods.

(4) Until such time as the Commission issues a regulation under paragraph (1) defining the term "combustible" as applied to liquids, such term shall apply to any liquid which has a flash point above eighty degrees Fahrenheit to and including one hundred and fifty degrees, as determined by the Tagliabue Open Cup Tester.

(m) The term "radioactive substance" means a substance which emits ionizing radiation.

(n) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the case of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (1) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (2) on all accompanying literature where there are directions for use, written or otherwise.

(o) The term "immediate container" does not include package liners.

(p) The term "misbranded hazardous substance" means a hazardous substance (including a toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted) intended, or packaged in a form suitable, for use in the household or by children, if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of this title or if such substance, except as otherwise provided by or pursuant to section 1262 of this title, fails to bear a label—

(1) which states conspicuously (A) the name and place of business of the manufacturer, packer, distributor or seller; (B) the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Secretary by regulation permits or requires the use of a recognized generic name; (C) the signal word "DANGER" on substances which are extremely flammable, corrosive, or highly toxic; (D) the signal word "WARNING" or "CAUTION" on all other hazardous substances; (E) an affirmative statement of the principal hazard or hazards, such as "Flammable", "Combustible", "Vapor Harmful", "Causes Burns", "Absorbed Through Skin", or similar wording descriptive of the hazard; (F) precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Secretary pursuant to section 1262 of this title; (G) instruction, when necessary or appropriate, for first-aid treatment; (H) the word "poison" for any hazardous substance which is defined as "highly toxic" by subsection (h) of this section; (I) instructions for handling and storage of packages which require special care in handling or storage; and (J) the statement (i) "Keep out of the reach of children" or its practical equivalent, or, (ii) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard, and

(2) on which any statements required under subparagraph (1) of this paragraph are located prominently and are in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

The term "misbranded hazardous substance" also includes a household substance as defined in section 1471(2)(C) of this title if it is a substance described in paragraph (1) of subsection (f) of this section and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of this title.

(q)(1) The term "banned hazardous substance" means (A) any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted; or (B) any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Secretary by regulation classifies as a "banned hazardous substance" on the basis of a finding that, notwith-

repealing sections 401 to 411 of this title] is declared unconstitutional, or the applicability thereof to any person or circumstance is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby."

Transfer of Functions. Functions of the Secretary of Health, Education, and Welfare under this chapter transferred to the Consumer Product Safety Commission, see section 2079 of this title.

The Atomic Energy Commission was abolished and all functions were transferred to the Administrator of the Energy Research and Development Administration (unless otherwise specifically provided) by section 5814 of Title 42, The Public Health and Welfare. The Energy Research and Development Administration was terminated and functions vested by law in the Administrator thereof were transferred to the Secretary of Energy (unless otherwise specifically provided) by sections 7151(a) and 7293 of Title 42.

Effect upon Federal and State Law. Pub. L. 86–613, § 18, formerly 17, July 12, 1960, 74 Stat. 380, as amended Pub.L. 89–756, § 4 (a), Nov. 3, 1966, 80 Stat. 1305; renumbered and amended Pub.L. 91–113, § 4(a), (b)(1), Nov. 6, 1969, 83 Stat. 189, 190; Pub.L. 94–284, § 17(a), May 11, 1976, 90 Stat. 510, provided that:

"(a) Nothing in this Act [adding this chapter and repealing sections 401 to 411 of this title] shall be construed to modify or affect the provisions of the Flammable Fabrics Act, as amended (15 U.S.C. 1191 to 1200) [sections 1191 to 1200 of this title], or any regulations promulgated thereunder; or of chapter 39, title 18, United States Code, as amended (18 U.S.C. 831 et seq.) [section 831 et seq. of Title 18], or any regulations promulgated thereunder or under sections 204(a)(2) and 204(a)(3) of the Interstate Commerce Act, as amended [section 304(a)(2), (3) of Title 49] (relating to the transportation of dangerous substances and explosives by surface carriers); or of section 1716, title 18, United States Code [section 1716 of Title 18], or any regulations promulgated thereunder (relating to mailing of dangerous substances); or of section 902 [section 1472 of Title 49] or regulations promulgated under section 601 of the Federal Aviation Act of 1958 [section 1421 of Title 49] (relating to transportation of dangerous substances and explosives in aircraft); or of the Federal Food, Drug, and Cosmetic Act [chapter 9 of Title 21]; or of the Public Health Service Act [chapter 6A of Title 42]; or of the Federal Insecticide, Fungicide, and Rodenticide Act [section 135 et seq. of Title 7]; or of the Dangerous Drug Act for the District of Columbia (70 Stat. 612), or the Act entitled 'An Act to regulate the practice of pharmacy and the sale of poisons in the District of Columbia, and for other purposes', approved May 7, 1906 (34 Stat. 175), as amended; or of any other Act of Congress, except as specified in section 19 [set out as a note under former sections 401 to 411 of this title].

"(b)(1)(A) Except as provided in paragraphs (2) and (3), if a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) [subsec. (p) of this section or section 1262(b) of this title] designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under section 2(p) or 3(b) [subsec. (p) of this section or section 1262(b) of this title].

"(B) Except as provided in paragraphs (2), (3), and (4), if under regulations of the Commission promulgated under or for the enforcement of section 2(q) [subsec. (q) of this section] a requirement is established to protect against a risk of illness or injury associated with a hazardous substance, no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations.

"(2) The Federal Government and the government of any State or political subdivision of a State may establish and continue in effect a requirement applicable to a hazardous substance for its own use (or to the packaging of such a substance) which requirement is designed to protect against a risk of illness or injury associated with such substance and which is not identical to a requirement described in paragraph (1) applicable to such substance (or packaging) and designed to protect against the same risk of illness or injury if the Federal, State, or political subdivision requirement provides a higher degree of protection from such risk of illness or injury than the requirement described in paragraph (1).

"(3)(A) Upon application of a State or political subdivision of a State, the Commission may, by regulation promulgated in accor-

(2) Proceedings for the issuance, amendment, or repeal of regulations under this subsection and the admissibility of the record of such proceedings in other proceedings, shall in all respects be governed by the provisions of section 371(e), (f), and (g) of Title 21, except that—

(A) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 348(f)(2) of Title 21; and

(B) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3) of section 348(g) of Title 21.

Reasonable variations or additional label requirements

(b) If the Secretary finds that the requirements of section 1261 (p)(1) of this title are not adequate for the protection of the public health and safety in view of the special hazard presented by any particular hazardous substance, he may by regulation establish such reasonable variations or additional label requirements as he finds necessary for the protection of the public health and safety; and any such hazardous substance intended, or packaged in a form suitable, for use in the household or by children, which fails to bear a label in accordance with such regulations shall be deemed to be a misbranded hazardous substance.

Exemption from requirements by regulation

(c) If the Secretary finds that, because of the size of the package involved or because of the minor hazard presented by the substance contained therein, or for other good and sufficient reasons, full compliance with the labeling requirements otherwise applicable under this chapter is impracticable or is not necessary for the adequate protection of the public health and safety, the Secretary shall promulgate regulations exempting such substance from these requirements to the extent he determines to be consistent with adequate protection of the public health and safety.

Exemption from requirements of this chapter of substances or containers adequately regulated by other provisions of law

(d) The Secretary may exempt from the requirements established by or pursuant to this chapter any hazardous substance or container of a hazardous substance with respect to which he finds that adequate requirements satisfying the purposes of this chapter have been established by or pursuant to any other Act of Congress.

Regulation of toys or articles intended for use by children

(e)(1) A determination by the Secretary that a toy or other article intended for use by children presents an electrical, mechanical, or thermal hazard shall be made by regulation in accordance with the procedures prescribed by section 553 (other than clause (B) of the last sentence of subsection (b) of such section) of Title 5 unless the Secretary elects the procedures prescribed by subsection (e) of section 371 of Title 21, in which event such subsection and subsections (f) and (g) of such section 371 of Title 21 shall apply to the making of such determination. If the Secretary makes such election, he

16 CODE OF FEDERAL REGULATIONS
§ 1500 ET SEQ.

product, but by all others in a household, especially children.

(8) The definition of "radioactive substance" in section 2(m) of the act (restated in paragraph (b)(11) of this section) is supplemented by the following: *Radioactive substance* means a substance which, because of nuclear instability, emits electromagnetic and/or particulate radiation capable of producing ions in its passage through matter. Source materials, special nuclear material, and byproduct materials described in section 2(f)(3) of the act are exempt.

(9) In the definition of "label" in section 2(n) of the act (restated in paragraph (b)(12) of this section), a provision stipulates that words, statements, or other information required to be on the label must also appear on all accompanying literature where there are directions for use, written or otherwise. To make this provision more specific, "accompanying literature" is interpreted to mean any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children.

(10) The definition of "misbranded hazardous substance" in section 2(p) of this act (restated in paragraph (b)(14) of this section) is supplemented by the following definitions or interpretations of terms used therein:

(i) *Hazardous substances intended, or packaged in a form suitable, for use in the household* means any hazardous substance, whether or not packaged, that under any customary or reasonably foreseeable condition of purchase, storage, or use may be brought into or around a house, apartment, or other place where people dwell, or in or around any related building or shed including, but not limited to, a garage, carport, barn, or storage shed. The term includes articles, such as polishes or cleaners, designed primarily for professional use but which are available in retail stores, such as hobby shops, for nonprofessional use. Also included are items, such as antifreeze and radiator cleaners, that although principally for car use may be stored in or around dwelling places. The term does not include industrial supplies that might be taken into a home by a serviceman. An article labeled as, and marketed solely for, industrial use does not become subject to this act because of the possibility that an industrial worker may take a supply for his own use. Size of unit or container is not the only index of whether the article is suitable for use in or around the household; the test shall be whether under any reasonably foreseeable condition of purchase, storage, or use the article may be found in or around a dwelling.

(ii) *Conspicuously* in section 2(p)(1) of the act and *prominently* and *conspicuous* in section 2(p)(2) of the act mean that, under customary conditions of purchase, storage, and use, the required information shall be visible, noticeable, and in clear and legible English. Some factors affecting a warning's prominence and conspicuousness are: Location, size of type, and contrast of printing against background. Also bearing on the effectiveness of a warning might be the effect of the package contents if spilled on the label.

NOTE: The definitions of *extremely flammable, flammable,* and *combustible* hazardous substances set forth above in paragraphs (b)(10) and (c)(6) are effective August 10, 1987. The definitions remaining in effect until August 10, 1987, as published at 38 FR 27012, Sept. 27, 1973, and amended at 38 FR 30105, Nov. 1, 1973, are set forth below. Manufacturers and labelers of products subject to the Federal Hazardous Substances Act may continue to use these definitions for labeling of those products under the conditions set forth in §1500.3(c)(6)(iv), as amended.

(b)(10) *Extremely flammable* shall apply to any substance which has a flashpoint at or below 20 °F. as determined by the Tagliabue Open Cup Tester; *flammable* shall apply to any substance which has a flashpoint of above 20 °F., to and including 80 °F., as determined by the Tagliabue Open Cup Tester; and *combustible* shall apply to any substance which has a flashpoint above 80 °F. to and including 150 °F., as determined by the Tagliabue Open Cup Tester; except that the flammability or combustibility of solids and of the contents of self-pressurized containers shall be determined by methods found

§ 1500.14 Products requiring special labeling under section 3(b) of the act.

(a) Human experience, as reported in the scientific literature and to the Poison Control Centers and the National Clearing House for Poison Control Centers, and opinions of informed medical experts establish that the following substances are hazardous:

(1) Diethylene glycol and mixtures containing 10 percent or more by weight of diethylene glycol.

(2) Ethylene glycol and mixtures containing 10 percent or more by weight of ethylene glycol.

(3) Products containing 5 percent or more by weight of benzene (also known as benzol) and products containing 10 percent or more by weight of toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates such as kerosine, mineral seal oil, naphtha, gasoline, mineral spirits, stoddard solvent, and related petroleum distillates.

(4) Methyl alcohol (methanol) and mixtures containing 4 percent or more by weight of methyl alcohol (methanol).

(5) Turpentine (including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine, and destructively distilled wood turpentine) and mixtures containing 10 percent or more by weight of such turpentine.

(b) The Commission finds that the following substances present special hazards and that, for these substances, the labeling required by section 2(p)(1) of the act is not adequate for the protection of the public health. Under section 3(b) of the act, the following specific label statements are deemed necessary to supplement the labeling required by section 2(p)(1) of the act:

(1) *Diethylene glycol.* Because diethylene glycol and mixtures containing 10 percent or more by weight of diethylene glycol are commonly marketed, stored, and used in a manner increasing the possibility of accidental ingestion, such products shall be labeled with the signal word "warning" and the statement "Harmful if swallowed."

(2) *Ethylene glycol.* Because ethylene glycol and mixtures containing 10 percent or more by weight of ethylene glycol are commonly marketed, stored, and used in a manner increasing the possibility of accidental ingestion, such products shall be labeled with the signal word "warning" and the statement "Harmful or fatal if swallowed."

(3) *Benzene, toluene, xylene, petroleum distillates.* (i) Because inhalation of the vapors of products containing 5 percent or more by weight of benzene may cause blood dyscrasias, such products shall be labeled with the signal word "danger," the statement of hazard "Vapor harmful," the word "poison," and the skull and crossbones symbol. If the product contains 10 percent or more by weight of benzene, it shall bear the additional statement of hazard "Harmful or fatal if swallowed" and the additional statement "Call physician immediately."

(ii) Because products containing 10 percent or more by weight of toluene, xylene, or any of the other substances listed in paragraph (a)(3) of this section may be aspirated into the lungs, with resulting chemical pneumonitis, pneumonia, and pulmonary edema, such products shall be labeled with the signal word "danger," the statement or hazard "Harmful or fatal if swallowed," and the statement "Call physician immediately."

(iii) Because inhalation of the vapor of products containing 10 percent or more by weight of toluene or xylene may cause systemic injury, such products shall bear the statement of hazard "Vapor harmful" in addition to the statements prescribed in paragraph (b)(3)(ii) of this section.

(4) *Methyl alcohol (methanol).* Because death and blindness can result from the ingestion of methyl alcohol, the label for this substance and for mixtures containing 4 percent or more by weight of this substance shall include the signal word "danger," the additional word "poison," and the skull and crossbones symbol. The statement of hazard shall include "Vapor harmful" and "May be fatal or cause blindness if swallowed." The label shall also bear the statement "Cannot be made nonpoisonous."

(5) *Turpentine.* Because turpentine (including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine, and

statement of conformance appear with art materials that have been reviewed in accordance with the Commission standard. The Commission interprets this provision to require a conformance statement regardless of the presence of any chronic hazard warnings.

(D) Nothing in this enforcement statement should be deemed to alter any of the requirements of the Federal Hazardous Substances Act ("FHSA"), such as, but not limited to, the requirement that any hazardous substance intended or packaged in a form suitable for household use must be labeled in accordance with section 2(p) of the FHSA.

APPENDIX A TO §1500.14(b)(8)—GUIDELINES FOR A CERTIFYING ORGANIZATION (NOT MANDATORY)

(a) The term "certifying organization," as used in this paragraph, refers to an organization or an institute that, after assuring that all provisions are met, certifies that an art material does conform to the labeling requirements of this practice.

(b) The certifying body may be funded by member manufacturers, but should include users or their representatives, as well as manufacturers' chemists, on its technical and certifying committees.

(c) Representative samples of art materials, labeled as conforming to this section and bought at retail, should be analyzed at random and from time to time by an analytical laboratory to ensure they are the same as the formulation used by the toxicologist(s) for determining labeling requirements.

(d) The methods used by the toxicologist(s) in review and determination of the need and content of precautionary labeling for potentially chronic adverse health effects should be periodically reviewed by an advisory board composed of not less than three or more than five toxicologists, at least one of whom is certified in toxicology by a nationally recognized certification board.

(e) In cases where there is disagreement by participating producers or participating users, with the determination of the toxicologist(s), there should be a method whereby the toxicologist's decision can be presented to the advisory board of toxicologists for arbitration.

[38 FR 27012, Sept. 27, 1973, as amended at 41 FR 22934, June 8, 1976; 48 FR 16, Jan. 3, 1983; 53 FR 3018, Feb. 3, 1988; 57 FR 46669, Oct. 9, 1992; 60 FR 8193, Feb. 27, 1995; 61 FR 19629, May 3, 1996; 61 FR 33175, June 26, 1996]

EFFECTIVE DATE NOTES: 1. At 61 FR 19629, May 3, 1996, §1500.14 was amended by redesignating paragraphs (b)(6) (i) and (ii) as (b)(6)(i)(A) and (B), amending newly designated paragraph (b)(6)(i)(A), amending newly designated paragraph (b)(6)(i)(B) by adding "packaged before November 3, 1997" after "charcoal", and adding a new paragraph (b)(6)(ii), effective Nov. 3, 1997.

2. At 61 FR 33175, June 26, 1996, a correction document was published that amended paragraph (b)(6)(i)(A) by adding "packaged before November 3, 1997" after "products" and changing "[insert date that is 18 months after publication]" to read "November 3, 1997," and amending paragraph (b)(6)(ii)(B) by changing "5⅛₆ inches" to read "5 1⅛₆ inches", effective Nov. 3, 1997.

§1500.15 Labeling of fire extinguishers.

When a substance or mixture of substances labeled for use in or as a fire extinguisher produces substances that are toxic within the meaning of §1500.3(c) (1) and (2) when used according to label directions to extinguish a fire, the containers for such substances shall bear the following labeling:

(a) When substances are produced that meet the definition of highly toxic in §1500.3(c)(1), the signal word "Danger" and the statement of hazard "Poisonous gases formed when used to extinguish flame or on contact with heat" are required labeling.

(b) When substances are produced that meet the definition of toxic in §1500.3(c)(2), the signal word "Caution" or "Warning" and the statement of hazard "Dangerous gas formed when used to extinguish flame or on contact with heat" are required labeling.

(c) Regardless of whether paragraph (a) or (b) of this section applies, any substance or mixture of substances labeled for use as a fire extinguisher that, if applied to an electrical fire, would subject the user to the likelihood of electrical shock shall be conspicuously labeled "Caution: Do not use on electrical wires."

(d) The statements specified in paragraphs (a), (b), and (c) of this section shall be in addition to any other that may be required under the act. All such substances or mixtures of substances shall also bear the additional statements "Use in an enclosed place may be fatal" and "Do not enter area until well ventilated and all odor of chemical has disappeared."

appropriate means having an accuracy of ±0.5 pound (±225 grams).

(3) *Testing procedure.* With the test sample fastened in a convenient position, and appropriate clamp shall be attached to the test object or component. A 15-pound ±0.5 pound (6.80-kilogram) direct force shall be evenly applied, within a period of 5 seconds, parallel to the major axis of the test component and maintained for an additional 10 seconds. The tension clamp shall then be removed and a second clamp appropriate for pulling at 90 degrees shall be attached to the test object or component. A 15-pound ±0.5 pound (6.80-kilogram) tensile force shall be evenly applied, within a period of 5 seconds, perpendicularly to the major axis of the test component and maintained for an additional 10 seconds.

(g) *Compression test*—(1) *Application.* Any area on the surface of a toy that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subject to this test.

(2) *Test apparatus.* The loading device shall be a rigid metal disc 1.125 inches ±0.015 inch (2.86 centimeters) in diameter and 0.375 inch (0.95 centimeter) in thickness. The perimeter of the disc shall be rounded to a radius of 1/32 inch (0.08 centimeter) to eliminate irregular edges. The disc shall be attached to an appropriate compression scale having an accuracy of ±0.5 pound (±225 grams).

(3) *Testing procedure.* The disc shall be positioned so that the contact surface is parallel to the surface under test. A direct force of 30 pounds ±0.5 pound (13.6 kilograms) shall be evenly applied within 5 seconds through the disc. This load shall be maintained for an additional 10 seconds. During the test the toy is to rest on a flat, hard surface in any convenient position.

[40 FR 1486, Jan. 7, 1975; 40 FR 16192, Apr. 10, 1975, as amended by 56 FR 10, Jan. 2, 1991]

§ 1500.81 Exemptions for food, drugs, cosmetics, and fuels.

(a) *Food, drugs, and cosmetics.* Substances subject to the Federal Food, Drug, and Cosmetic Act are exempted by section 2(f)(2) of the act; but where a food, drug, or cosmetic offers a substantial risk of injury or illness from any handling or use that is customary or usual it may be regarded as misbranded under the Federal Food, Drug, and Cosmetic Act because its label fails to reveal material facts with respect to consequences that may result from use of the article (21 U.S.C. 321(n)) when its label fails to bear information to alert the householder to this hazard.

(b) *Fuels.* A substance intended to be used as a fuel is exempt from the requirements of the act when in containers that are intended to be or are installed as part of the heating, cooling, or refrigeration system of a house. A portable container used for delivery or temporary or additional storage, and containing a substance that is a hazardous substance as defined in section 2(f) of the act, is not exempt from the labeling prescribed in section 2(p) of the act, even though it contains a fuel to be used in the heating, cooking, or refrigeration system of a house.

§ 1500.83 Exemption from full labeling and other requirements.

(a) Any person who believes a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from full label compliance otherwise applicable under the act, because of the size of the package or because of the minor hazard presented by the substance, or for other good and sufficient reason, may submit to the Commission a request for exemption under section 3(c) of the act, presenting facts in support of the view that full compliance is impracticable or is not necessary for the protection of the public health. The Commission shall determine on the basis of the facts submitted and all other available information whether the requested exemption is consistent with adequate protection of the public health and safety. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order published in the FEDERAL REGISTER.

(b) The Commission may on its own initiative determine on the basis of facts available to it that a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from full labeling compliance otherwise applicable under the act because of the size of the package or

the same type size as that required in Table 1 for the other cautionary material which appears elsewhere on the label of a hazardous substance. The size of the cautionary labeling that does not appear on the principal display panel is determined by the area of the panel on which it does appear.

(3) *Type style—proportion.* The ratio of the height of a capital or uppercase letter to its width shall be such that the height of the letter is no more than 3 times its width.

(4) *Signal word and statements of hazard—capital letters.* The signal word, the word "poison" if required instead of a signal word (see §1500.129), and the statement of principal hazard or hazards shall be in capital letters.

(5) *Multiple statement of hazard—type size and style.* All statements of principal hazard or hazards on a label shall appear in the same size and style of type, and shall appear in the same color or have the same degree of boldness.

(6) *Accompanying literature containing directions for use.* Where literature accompanying the package of a hazardous substance has directions for use, written or otherwise, section 2(n) of the Act requires the literature to bear cautionary labeling.

(i) All such cautionary labeling shall be in reasonable proximity to any direction for use and shall be placed together within the same general area.

(ii) The type size of such cautionary labeling shall be reasonably related to the type size of any other printed matter in the accompanying literature and must be in conspicuous and legible type by typography, layout, or color with other printed matter on the label. The signal word and statement of principal hazard or hazards shall appear in capital letters.

(d) *Conspicuousness—contrast.* To satisfy the requirement that cautionary labeling statements appear in conspicuous and legible type which is in contrast by typography, layout, or color with the other printed matter on the label, such statements shall conform to the following requirements:

(1) *Color.* Where color is the primary method used to achieve appropriate contrast, the color of any cautionary labeling statement shall be in sharp contrast with the color of the background upon which such a statement appears. Examples of combinations of colors which may not satisfy the requirement for sharp contrast are: black letters on a dark blue or dark green background, dark red letters on a light red background, light red letters on a reflective silver background, and white letters on a light gray or tan background.

(2) *Interference with conspicuousness—labeling design, vignettes, or other printed material.* For cautionary information appearing on panels other than the principal display panel, the label design, the use of vignettes, or the proximity of other labeling or lettering shall not be such that any cautionary labeling statement is obscured or rendered inconspicuous.

(e) *Collapsible metal tubes.* Collapsible metal tubes containing hazardous substances shall be labeled so that all cautionary labeling required by the Act appears as close to the dispensing end of the container as possible. The placement and conspicuousness of these statements shall conform to the provisions of paragraphs (b), (c), and (d) of this section.

(f) *Unpackaged hazardous substances.* Where practicable, unpackaged hazardous substances intended, or distributed in a form suitable, for use in or around a household or by children shall be labeled so that all items of information required by the Act appear upon the article itself. In instances where this is impracticable (for example, because of the size or nature of the article), the required cautionary labeling must be displayed by means of a tag or other suitable material that is no less than five square inches in area and is securely affixed to the article so that the labeling will remain attached throughout conditions of merchandising and distribution to the ultimate consumer. The placement and conspicuousness of all cautionary labeling appearing on such a tag or material, or on an unpackaged article, shall conform to the provisions of paragraphs (b), (c), and (d) of this section. For the purposes of determining the proper type size to use on a tag or other material, the area of one side of the tag or other

material shall be the area of the principal display panel.

(g) *Exemptions.* All requirements of the Act are satisfied by compliance with this §1500.121. However, exemptions can be granted under section 3(c) of the Act and §1500.83, or under the provisions of another statute should this section be incorporated in regulations under another statute. Section 1500.82 contains the requirements for exemption requests under the Federal Hazardous Substances Act.

(h) *Effective date.* The provisions of this rule apply to hazardous substances bearing labels printed after December 30, 1985. Labels printed prior to the effective date of this rule may be applied until not later than December 28, 1987. This rule applies to all hazardous substances to which labels are applied after December 28, 1987.

[49 FR 50383, Dec. 28, 1984]

§ 1500.122 Deceptive use of disclaimers.

A hazardous substance shall not be deemed to have met the requirements of section 2(p) (1) and (2) of the act (repeated in §1500.3(b)(14) (i) and (ii)) if there appears in or on the label (or in any accompanying literature; words, statements, designs, or other graphic material that in any manner negates or disclaims any of the label statements required by the act; for example, the statement "Harmless" or "Safe around pets" on a toxic or irritant substance.

§ 1500.123 Condensation of label information.

Whenever the statement of the principal hazard or hazards itself provides the precautionary measures to be followed or avoided, a clear statement of the principal hazard will satisfy the requirements of section 2(p)(1) (E) and (F) of the act (repeated in §1500.3(b)(14)(i) (E) and (F)). When the statement of precautionary measures in effect provides instruction for first-aid treatment, the statement of the precautionary measures will satisfy the requirements of section 2(p)(1) (F) and (G) of the act (repeated in §1500.3(b)(14)(i) (F) and (G)).

§ 1500.125 Labeling requirements for accompanying literature.

When any accompanying literature includes or bears any directions for use (by printed word, picture, design, or combination thereof), such placard, pamphlet, booklet, book, sign, or other graphic or visual device shall bear all the information required by section 2(p) of the act (repeated in §1500.3(b)(14)).

§ 1500.126 Substances determined to be "special hazards."

Whenever the Commission determines that for a particular hazardous substance intended or packaged in a form suitable for use in the household or by children, the requirements of section 2(p) of the act (repeated in §1500.3(b)(14)) are not adequate for the protection of the public health and safety because of some special hazard, the Commission, by an appropriate order in the FEDERAL REGISTER, shall specify such reasonable variations or additional label requirements that it finds are necessary for the protection of the public health and safety. Such order shall specify a date that is not less than 90 days after the order is published (unless emergency conditions stated in the order specify an earlier date) after which any such hazardous substance intended, or packaged in a form suitable, for use in the household or by children that fails to bear a label in accordance with such order shall be deemed to be a misbranded hazardous substance.

§ 1500.127 Substances with multiple hazards.

(a) Any article that presents more than one type of hazard (for example, if the article is both toxic and flammable) must be labeled with: An affirmative statement of each such hazard; the precautionary measures describing the action to be followed or avoided for each such hazard; instructions, when necessary or appropriate, for first-aid treatment of persons suffering from the ill effects that may result from each such hazard; instructions for handling and storage of articles that require special care in handling and storage because of more than

(2)

No. 97-615

Supreme Court, U.S.
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In the Supreme Court of the United States

OCTOBER TERM, 1997

TRUSERV CORPORATION, PETITIONER

v.

THE PEOPLE OF THE STATE OF CALIFORNIA, EX REL. DANIEL G. LUNGREN, ATTORNEY GENERAL, AND AS YOU SOW, RESPONDENTS

On Petition for a Writ of Certiorari to the California Court of Appeal, First Appellate District

REPLY BRIEF FOR PETITIONER

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15 pp

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

A. The Issues Presented In This Case Are Neither "Narrow" Nor Identical To Those Raised in *Allenby* . . . 1

B. The State's Efforts To Explain Away The Conflicts And Confusion In The Lower Courts Are Unsuccessful 4

C. The Issues Presented Are Recurring And Important 6

D. The Decision Below Is Manifestly Incorrect 8

CONCLUSION 11

TABLE OF AUTHORITIES

Pages

Cases:

Chemical Specialties Mfrs. Ass'n, Inc. v. *Allenby*, 958 F.2d 941 (9th Cir.), cert. denied, 506 U.S. 825 (1992) . . . . . *passim*

Cipollone v. *Liggett Group, Inc.*, 505 U.S. 504 (1992) . . . . . *passim*

Industrial Truck Ass'n v. *Henry*, 1997 WL 594619 (9th Cir. Sept. 29, 1997) 2

Kernats by Kernats v. *Smiths Industries Medical Systems, Inc.*, 669 N.E.2d 1300 (Ill. App. Ct.), appeal denied, 675 N.E.2d 634 (Ill. 1996), pet. for cert. filed, 65 U.S.L.W. 3632 (Mar. 4, 1997) (No. 96-1405) 10

Lewis v. *Brunswick Corp.*, No. 97-288 . . . . . 1, 10

Medtronic, Inc. v. *Lohr*, 116 S. Ct. 2240 (1996) . . . . . *passim*

National Broiler Council v. *Voss*, 44 F.3d 740 (9th Cir. 1994) 5

New York State Pesticide Coalition, Inc. v. *Jorling*, 874 F.2d 115 (2d Cir. 1989) 5

Papas v. *Upjohn*, 985 F.2d 516 (11th Cir.), cert. denied, 510 U.S. 913 (1993) 4

Taylor AG Indus. v. *Pure-Gro*, 54 F.3d 555 (9th Cir. 1995) 2

Statutes and Regulations:

15 U.S.C. § 1261(n) 9

16 C.F.R. § 1500.3(c)(9) 9

TABLE OF AUTHORITIES — Continued

Miscellaneous: **Pages**

Bill Analysis, Assembly Committee on Environmental Safety and Toxic Materials (Apr. 16, 1996) 7, 8

Dorf, *Facial Challenges to State and Federal Statutes*, 46 Stan. L. Rev. 235 (1994) 10

O'Reilly, *Stop The World, We Want Our Own Labels*, 18 U. Pa. J. Int'l Econ. L. 617 (1997) 7, 8

S. Rep. No. 251, 94th Cong., 2d Sess., *reprinted in* 1976 U.S.C.C.A.N. 993 . . . . . 9, 10

Woody, *Efforts to Control Prop 65 Litigation Are Heating Up*, The Recorder 1 (May 17, 1996) 7

REPLY BRIEF FOR PETITIONER

This case presents the Court with the opportunity to resolve substantial conflicts over the scope of preemption under the FHSA, an important statute that governs thousands of household products. Pet. 9-11, 19, 21. Review would also permit the Court to resolve conflicts over the preemptive effect of other closely related statutes and the applicability of the "general/specific" distinction employed by this Court in *Medtronic* to statutes other than the MDA. Pet. 11-14, 16-19.[1] Some 15 federal statutes expressly preempt state "labeling" requirements, so the issues presented are undeniably recurring as well as important to the proper administration of federal law, and the lower court's resolution of them was marred by serious error. Pet. 21-30.

California does its best to sow confusion about the scope of the holding below and create doubt about the extent of the conflicts in the lower courts. Try as it might, though, the State is unsuccessful in its efforts to explain away the disagreements in the lower courts, minimize the importance of the issues presented, or defend the indefensible logic of the Court of Appeal's decision.

A. The Issues Presented In This Case Are Neither "Narrow" Nor Identical To Those Raised in *Allenby*.

The State's brief repeatedly asserts that "the issue" in this case is "narrow" (Br. in Opp. ii, 2, 10, 17, 26) or even "peculiarly narrow" (*id.* at 10) and "not likely to arise again" because it has been definitively resolved by the federal and state courts in California (*id.* at 2, 10). Relatedly, the State suggests that this case is just a carbon copy of the Ninth Circuit's 1992 decision in *Allenby*, which this Court declined to review. Br. in Opp. 2, 6-7, 15, 26. Neither of the State's major themes is correct.

1. The issue presented in this case is not limited to "whether

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[1] The Court's grant of review in *Lewis* v. *Brunswick Corp.*, No. 97-288, a case involving Boat Safety Act preemption, reflects recognition of the need for clarification of preemption law. Although the pendency of *Lewis* suggests that this case should *at least* be held, plenary review would be more appropriate because of the differences between the cases. In *Lewis*, the court of appeals held that a federal decision *not* to require propeller guards preempts state-law claims.

a point of sale sign containing the language" mandated by Proposition 65 "*is a direction for use* and therefore * * * preempted by the FHSA." Br. in Opp. 10 (emphasis added). *One argument* TruServ will make if review is granted is that the Court of Appeal erred in refusing to give deference to the CPSC's eminently reasonable interpretation of the phrase "directions for use," which is found in an FHSA provision that also defines the term "label." See Pet. 26-27. But at least two other arguments for reversal in no way depend on an interpretation of "directions for use." *First*, the Court of Appeal erred in refusing to interpret the term "labeling," which the FHSA does *not* define, by reference to various federal statutes that define this term of art (and that do so in a way that plainly encompasses point-of-sale signs, regardless of whether such signs include "directions for use"). Pet. 28-29. *Second*, the obligation under Proposition 65 to provide warnings in a point-of-sale sign is preempted even if such a sign is not a "label" or "labeling" and even if the warnings are not "directions for use," because the FHSA's preemption of state "cautionary labeling requirements" includes any state requirement to provide warnings *that is premised upon a deficiency in the product's "label" or "labeling."* Pet. 25-26.

Equally mistaken is California's suggestion (Br. in Opp. 10) that the question whether Proposition 65 warnings in point-of-sale signs are preempted by the FHSA is unlikely to arise again. As we explained (Pet. 14), *Allenby*'s key holding — which the California Court of Appeal in this case rejected — is that FIFRA cases are binding in cases involving FHSA preemption because the preemptive scope of the two statutes is identical. That principle, in turn, would oblige the federal courts in the Ninth Circuit to follow a line of post-*Allenby* cases that the court below found it necessary to distinguish (Pet. App. 17a-21a), including *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555 (9th Cir. 1995), all of which held that state-imposed obligations to provide warnings in point-of-sale signs are preempted "labeling" requirements under FIFRA. See also *Industrial Truck Ass'n* v. *Henry*, 1997 WL 594619 (9th Cir. Sept. 29, 1997) (holding that OSHA preempts Proposition 65 warnings without applying "general/specific" framework of *Medtronic*). The federal and state courts are far apart in their analysis, and future litigation over this issue is inevitable.

2. The State repeatedly suggests that the decision in this case is nothing more than a carbon copy of the Ninth Circuit's decision in *Allenby* and that the arguments raised here were also raised in the unsuccessful certiorari petition in *Allenby*. Br. in Opp. 2, 6-7, 26. That argument is flawed at every turn.

Allenby predated both *Cipollone* and *Medtronic*. The Court of Appeal in this case also *expressly disagreed* with *Allenby* in several respects. See Pet. App. 12a n.9, 19a n.16. In addition, *Allenby* involved a declaratory judgment action raising a facial challenge to the FHSA's preemption provision. Pet. 15-16. This case, in contrast, is an enforcement action in which TruServ raised a preemption defense that, by its nature, embodies an *as-applied* challenge to Proposition 65. The two cases are far from identical.

Respondent is also wrong to suggest (Br. in Opp. 6-7) that our petition merely rehashes arguments that were made in the *Allenby* petition. Virtually all of the cases involved in the various conflicts we identify have been decided since *Allenby*. Indeed, several of these conflicts in the lower court decisions are directly attributable to ambiguities in *Cipollone* and *Medtronic* (see Pet. 13, 16-18). Similarly, the conflict over whether FHSA and FIFRA preemption are coextensive was created, in large measure, by the lower court's action in *expressly disagreeing* on this point with *Allenby* and with other decisions. Pet. 14; Pet. App. 19a n.16. Not one of these conflicts existed at the time of *Allenby*.

The *Allenby* petition argued only that the legislative history of FHSA demonstrates Congress's goal of ensuring uniformity of hazardous substances labeling, that warnings in point-of-sale signs are *impliedly* preempted, and that the Ninth Circuit erred in failing to consider the CPSC General Counsel's interpretation of the FHSA preemption provision in Advisory Opinion No. 312. No. 91-1957 Pet. 24-28. Although Advisory Opinion No. 312 was cited in the *Allenby* petition, the Ninth Circuit's decision made no mention of it and the State itself argued in opposing certiorari that it "was not part of the record" and thus could not properly be considered. No. 91-1957 Br. for Cal. Atty. Gen. in Opp. 16. It is thus untrue that "eight different judges" (including the trial and appellate judges in *Allenby*) have concluded that the CPSC's interpretation is "contrary to the language of the statute." Br. in Opp. 15.

B. The State's Efforts To Explain Away The Conflicts And Confusion In The Lower Courts Are Unsuccessful.

Multiple aspects of the Court of Appeal's decision implicate disagreements among the federal and state courts. See Pet. 9-12, 14, 17-19. In several respects the Court of Appeal's holding also depends on reasoning that is at odds with this Court's decisions in *Cipollone* and *Medtronic*. See Pet. 14-16, 20. The State's arguments for why these conflicts are either nonexistent or not implicated by the lower court's holding are utterly lacking in merit.

1. The State incorrectly asserts that the conflicts (see Pet. 9-12) in the FHSA and FIFRA cases relating to whether non-label warnings are preempted are "illusory." Br. in Opp. 17.

a. The cases involving FHSA preemption, the State argues, are distinguishable because "all were based on common law failure to warn claims that *directly challenged* the adequacy of the label." Br. in Opp. 17 (emphasis added). That is precisely our point: a failure to warn claim *"necessarily* challenge[s] the adequacy of the warnings provided *on the product's labeling or packaging."* *Papas* v. *Upjohn*, 985 F.2d 511, 519 (11th Cir.), cert. denied, 510 U.S. 913 (1993). If the State is suggesting that these cases are inapposite because the only failure to warn at issue was a failure to warn *through the product label*, that argument rests on a misreading of these cases. Every one of these cases involved a claim under state law for *failure to warn* (not *failure to label*). Warnings can be conveyed by many methods, not just in the product's "label" or "labeling." See Pet. 9. Nor does is matter, as the State maintains (Br. in Opp. 19), that the state requirements at issue in these FHSA cases were imposed by the common law instead of by statute. See Pet. 14-15 (explaining why this distinction is inconsistent with *Cipollone* and *Medtronic*).

b. The State fares no better in seeking to explain away the pervasive conflict in the FIFRA cases (Pet. 11-12). It acknowledges that numerous courts have held that FIFRA's preemption of state "labeling" requirements reaches common law duties to warn "outside the label," including specifically in point-of-sale signs. Br. in Opp. 20 & n.11. The State also concedes that "[a] long line of cases" have held that "common law failure to warn claims" are preempted in their entirety by FIFRA. *Id.* at 20 & n.9. The State

further agrees that another line of cases "under FIFRA and similar federal laws" — including the Second Circuit's *Jorling* decision — reaches precisely the opposite result. Br. in Opp. 21-22.[2] The only explanation offered for the "obvious and distinct" conflict between these two lines of cases is, once again, the fact that one line involves common law requirements whereas the other involves statutory requirements. That is a distinction without a difference.

Taking a page from the Court of Appeal (see Pet. App. 17a-19a & nn.16-17), the State maintains that FIFRA preemption cases are inapplicable to cases involving the FHSA because (1) FIFRA, unlike FHSA, *does* include a definition of "labeling"; and (2) "the EPA approves the actual label under FIFRA." Br. in Opp. 23-24. Although it is true that FIFRA contains a broad definition of "labeling," none of the courts that have held that FIFRA preempts non-label warnings has relied on that fact. Instead, those courts, following *Cipollone* (see Pet. 13), have reasoned that the imposition of a state non-label warning requirement is *necessarily* premised on a deficiency in the product's "label." Nor does the fact that EPA approves FIFRA labeling (but CPSC does not approve FHSA labeling) render the FIFRA cases inapposite. The absence of agency approval of labeling is irrelevant in this case because the toluene warnings were *specifically mandated* by federal statute and regulation. See Pet. 2-3.

2. We demonstrated (Pet. 14) that the Court of Appeal's decision is at odds with many decisions holding that FHSA and FIFRA preemption are coextensive. We also showed that the lower court's analysis is inconsistent with a number of post-*Medtronic* decisions that have refused to transplant the "general/specific" distinction to statutes other than the MDA. Pet. 17-19 & nn. 9-10. The State acknowledges the existence of these conflicts (Br. in Opp. 17, 19, 24), but argues that they are not decisive to the outcome here. That argument is wrong.

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[2] Indeed, the State adds several cases to the latter group that were not cited in our petition, thus showing that the conflict we identified is *even deeper*. Br. in Opp. 21-22. Respondent is wrong, however, to include *National Broiler Council* v. *Voss*, 44 F.3d 740, 748-49 (9th Cir. 1994) (per curiam). The cited portion of *Voss* involved severability.

The Court of Appeal's holding was plainly dependent on the *Medtronic* "general/specific" distinction. The court derived from *Medtronic* the principle that "courts should broadly interpret the preemption provision of federal statutes with limited applicability and narrowly interpret those statutes with general applicability" (Pet. App. 9a); and it relied on that principle not only in ruling that *Cipollone* was inapplicable (Pet. App. 12a-14a) but also in deciding to give a narrow construction to the preemption provision of the FHSA, which the court regarded as a "general statute" (*id.* at 13a, 15a). The court also relied on *Medtronic* in distinguishing cases decided under FIFRA. Pet. App. 18a. The Court of Appeal even relied on *Medtronic*'s "general/specific" distinction in narrowly construing the term "directions for use" in the FHSA. See Pet. App. 15a. Because the Court of Appeal's construction of that term formed the basis for its refusal to defer to the CPSC's interpretation of "directions for use," the *Medtronic* analysis was decisive in this aspect of the decision as well.

It is also wrong to say that the Court of Appeal's holding — in express disagreement with *Allenby* — that FIFRA and FHSA preemption are not coextensive "is not dispositive of this case." Br. in Opp. 24. The Court of Appeal relied on that conclusion as a basis for refusing to follow a long line of FIFRA cases under which TruServ would have prevailed. Pet. App. 17a-21a.

3. The petition also identified several ways in which the Court of Appeal's holding depends on reasoning that is at odds with this Court's decisions in *Cipollone* and *Medtronic*. See Pet. 14-15, 19-20. The State makes no attempt to reconcile the Court of Appeal's maxim of construction with *Medtronic*. And it offers only the barest rejoinder to our demonstration that the distinction between common law and statutory requirements is unsustainable after *Cipollone* and *Medtronic*. The State asserts (Br. in Opp. 25) that the meaning of "requirement" is not at issue in this case, but that is irrelevant to the validity of the common law/statutory distinction that underlies the decision below.

C. The Issues Presented Are Recurring And Important.

Other than its efforts to portray the questions presented as much narrower than they really are, the State has little to say in response to our detailed showing (Pet. 21-25) of importance. It

does not dispute the broad applicability of the FHSA, the frequency with which FHSA preemption issues are litigated, or the existence of many federal statutes that, like the FHSA, preempt state "requirements" relating to product "labeling." Neither does the State dispute that the decision below will seriously impair the FHSA preemption provision as well as undermine the CPSC's general authority to enforce the statute in California. Pet. 24-25.

The State does, however, seek to minimize the significance of Proposition 65 by pointing out that no other State has yet followed California's lead. But Massachusetts is currently considering adopting a statute patterned after Proposition 65, and various other States have considered doing so. See Pet. 24. Even if no State will ever adopt a provision patterned after Proposition 65, that would hardly render this case unworthy of the Court's attention.

Proposition 65 has had an "extraordinary impact" on "marketing in the United States." O'Reilly, *Stop The World, We Want Our Own Labels*, 18 U. Pa. J. Int'l Econ. L. 617, 632-34 (1997). By requiring the payment of "a twenty-five percent 'bounty' from the [fines recovered] * * * to anyone who sues and wins as a private enforcer," Proposition 65 has created a "mini-industry of bounty hunter enforcement" and forced manufacturers to settle even frivolous cases in order to avoid crippling liability. *Id.* at 634. The sheer volume of Proposition 65 complaints is enormous. See Woody, *Efforts to Control Prop 65 Litigation Are Heating Up*, The Recorder, at 1 (May 17, 1996) (noting that respondent As You Sow alone "has filed some thousand intent-to-sue notices since 1992" and is "racking up millions of dollars in fees by forcing companies to settle minor or worthless complaints").[3] Moreover,

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[3] Assembly Bill 3160, which was sponsored by the California Attorney General and which would have placed new limits on private enforcement actions under Proposition 65, was defeated in the California Assembly when it failed to muster the 2/3 vote required by Proposition 65 to amend that law. Based on its investigation, the Committee on Environmental Safety and Toxic Materials, which reported AB 3160 out favorably, found that various public interest "litigation mills" in California had misused Proposition 65 by "unabashedly" and relentlessly "pursuing * * * small businesses with bogus legal action or threats of action for the single purpose of extorting money." Bill Analysis, Assembly Committee on

armed with Proposition 65's threat of massive liability, public and private enforcers routinely have secured settlements (as in this case, see Pet. 5 & n.2, Pet. App. 33a-34a) calling for businesses with nationwide operations to alter the *labels* of their nationally distributed products to include Proposition 65 warnings.[4] The issues raised in this case thus are of national importance.

D. The Decision Below Is Manifestly Incorrect.

There is no reason to countenance these severe dislocations, because the decision below is demonstrably incorrect. The State's efforts to defend the decision are unavailing.

1. The State disputes our contention (Pet. 25-26) that any state warning requirement that is premised on a deficiency in the federally required "label" or "labeling" is a "cautionary * * * requirement" relating to "labeling" and thus expressly preempted by the FHSA. According to the State, this argument is "directly contrary to the express language of the statute" and amounts to a claim that "Congress has implicitly occupied the entire field of warnings." Br. in Opp. 9; see also *id.* at 11-12.

The statutory text, however, supports our argument. The FHSA preempts certain "cautionary labeling requirements." California assumes, without explanation, that a "cautionary labeling requirement" is a requirement to make cautionary statements *in* the product's "labeling." But as the vast majority of federal and state courts have held (see Pet. 9-12, 23 n.15), it is more plausible to read the phrase "cautionary labeling requirement" to include a state requirement to make cautionary statements *that is premised*

Environmental Safety and Toxic Materials, at 3 (Apr. 16, 1996).

[4] In consumer product cases, the practice has been to calculate the potential liability by multiplying the $2500 penalty not by the number of days but by the *total number of product units sold*. Cf. O'Reilly, 18 U. Pa. J. Int'l Econ. L. at 632 n.84. Under that formula, TruServ's potential liability would have been enormous: this case involved hundreds of thousands of units of approximately 160 different products sold at more than 350 True Value® Hardware stores in California.

on a defect in the product's "labeling."[5]

The State is also wrong to characterize this argument as one of expansive "field preemption." By its plain terms, the FHSA preemption provision is limited to state "cautionary labeling requirements" that (a) target the same risk as a federal requirement, (b) are not identical to that requirement, and (c) have not been exempted by the CPSC.[6]

2. The CPSC and the FDA have long endorsed a broad understanding of FHSA "labeling" that encompasses point-of-sale signs. See Pet. 28-29. Ignoring that settled regulatory interpretation, the State asserts (but fails to demonstrate) that the FHSA uses the terms "labeling" and "label" "interchangeably." Br. in Opp. 13-14. The State also claims that our argument for incorporation of "labeling" as a term of art under federal law is "futile" because a CPSC regulation defines "accompanying literature" narrowly "to include only literature that provides directions for use." *Id.* at 14. The pertinent CPSC regulation, however, does not define "accompanying literature" for all purposes but rather as that term is specifically and restrictively used in 15 U.S.C. § 1261(n). See 16 C.F.R. § 1500.3(c)(9).[7]

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[5] This interpretation finds substantial support in the text of the preemption provision (which indicates that a "cautionary labeling requirement" is something that can be "applicable to" not just the "packaging" of a hazardous substance but also the "substance" itself, see Pet. 26), in the FHSA's legislative history (Pet. 25-26), and in common sense (because it prevents the States from avoiding preemption through the simple expedient of requiring warnings in point-of-sale signs rather than in product labels). California does not answer any of these points.

[6] To our knowledge, California has never asked the CPSC to exempt Proposition 65 from preemption.

[7] The State asserts that Congress "narrowed" the FHSA preemption provision in 1976 and "specifically rejected the idea of imposing uniform national labeling requirements." Br. in Opp. 4-5 (citing S. Rep. No. 251). In fact, the primary purpose of the 1976 amendment was to create *uniformity* in the preemption clauses of four statutes; and the only change in the scope of FHSA preemption noted by the Committee was an

3. The State insists that the Court of Appeal was right to apply the exacting standard for facial challenges to TruServ's assertion of a preemption defense in this enforcement action. Br. in Opp. 25. That proposition is absurd. TruServ did not bring a lawsuit to try to invalidate Proposition 65, but *defended* itself against the Attorney General's assertion that *particular actions* constituted a punishable violation of that statute. That is not a facial challenge. See generally Dorf, *Facial Challenges to State and Federal Statutes*, 46 Stan. L. Rev. 235, 236-42 (1994).[8]

4. At the end of the day, the State simply offers no good reason why Congress would have designed a preemption provision that nullifies state-imposed obligations to provide warnings in product labels but allows States to require the very same (or even more prominent) warnings in point-of-sale signs posted right next to the same products on the shelf. It offers no reason, and there is none, why point-of-sale signs are preempted by FHSA if they contain "directions for use" (as that term was narrowly understood by the Court of Appeal), but not if they lack directions for use. Such irrational distinctions should not be attributed to Congress.

This case warrants plenary review by this Court. Moreover, given the many federal statutes that preempt state "requirements" relating to product "labeling" (Pet. 22-23 & n.14), and the disregard of the CPSC's views in the decision below, the Court should at least invite the United States to express its views. In addition, and for reasons stated in the petition (at 21 n.13) and above (at note 1), this case should at least be held pending the disposition of the petition in No. 96-1405, *Smiths Industries* v. *Kernats*, and/or the decision in *Lewis* v. *Brunswick Corp.*, No. 97-288.

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expansion of FHSA preemption to accord preemptive effect to "regulations * * * used to determine when a hazardous substance * * * shall be banned." S. Rep. No. 251, at 11-12, 17, *reprinted in* 1976 U.S.C.C.A.N. at 1003-04, 1009; see Pet. 22, 29 n.18. The page of the Senate Report cited by California *endorses* the goal of uniformity while recognizing CPSC's authority to grant exemptions from preemption.

[8] Contrary to the State's suggestion (Br. in Opp. 8 n.4), TruServ's "de facto" labeling argument represents only one of several versions of petitioner's as-applied challenge in this case and has not been abandoned.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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